CLINICAL LABORATORIES (Part 2)

HEARING

BEFORE THE

SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON
ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

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CLINICAL LABORATORIES

WEDNESDAY, APRIL 29, 1992

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:25 p.m., in room 2123, Rayburn House Office Building, Hon. John D. Dingell (chairman) presiding.

Mr. DINGELL. The subcommittee will come to order.

Today, the subcommittee is very pleased to have Secretary Sullivan with us to discuss an issue that is of critical importance not only to this subcommittee but to the committee and to the public that is served by the HHS and by the committee. While the subcommittee has conducted numerous hearings involving public health policy and problems, today's hearing will focus on the Department's implementation of the Clinical Laboratory Improvement Amendments of 1988, also known as CLIA.

What we have heard at previous hearings is that there are more than enough villains responsible for the mess that our health-care delivery system has become. Many in the industry are motivated, regrettably, by avarice. Many patients have unrealistic expectations and continue to want everything at little or no cost to themselves.

Government administrators are choking themselves, providers, and insurers with their own paperwork glut, and often, well-intentioned policymakers pass laws designed to make more services available to more patients, to save taxpayers' money, and to improve the quality of care, only to find out too late that the laws have had precisely the opposite effect.

Unfortunately, the investigations of this subcommittee have led us to question whether we are witnessing bureaucratic bungling, political posturing, coddling of special interests in the medical industrial complex, or all of the above. What is clear is that the losers are the American public, American industry, and the American economy. What is often even more difficult is separating fact from fiction.

The effort to implement the reform of this country's regulation of laboratory testing is one very troublesome example. This subcommittee has a long history of interest in the Clinical Laboratory Improvement Amendments of 1988. That act was created by this committee, and many of the members of this subcommittee actively involved themselves in its strongly bipartisan passage. These reforms were widely supported because it became unavoidably clear

that we simply could not rely on the accuracy of laboratory testing that was literally life and death in its consequences to the patients.

It is little exaggeration to say that, over 3½ years later, we are no closer than we were before to achieving the goal of that act. The Department's implementation of this act is a textbook case of how things should not be done.

The subcommittee's record demonstrates a consistent pattern of delay, the failure to gather even the most basic information on where the laboratories are, who is performing what kinds of tests, and whether these tests are being performed accurately.

The record also demonstrates a curious aversion to capitalizing on the experience of other regulators and other experts who have traveled these roads before the Department. Instead, the Department has chosen to conduct hearings which are not public and of which there are no transcripts. This committee finds that curious. Consequently, it is totally unclear whether the meetings which were held in secret account for the reversals that the Department has suffered and other anomalies which exist in this regulatory process. We have little idea of how and why the Department arrived at its final version in the regulations, which differs significantly from those originally proposed. Hopefully, the Secretary will be able to assist the committee in some intelligent conclusions on these perplexing questions.

All this is not to suggest that we are displeased with everything that the Department has done on a substantive level.

For example, the subcommittee is very gratified that the Department has recognized urine tests as a fundamental device for prying into a test subject's health. On-site drug-screening laboratories, heretofore totally unregulated, will now be properly required to comply with at least some minimal quality regulations and requirements. This may even be reason to postpone, for the time being, further consideration of H.R. 33, the bill cosponsored by the distinguished gentleman from Virginia, Mr. Bliley, and I—the Drug Testing Quality Act—to give the subcommittee and this committee time to evaluate the effect of the new regulations.

However, we do know that many experts believe that the final product can be a hopeless hodgepodge that is simply not workable. While the Department has charged that the act was so seriously flawed that implementation is virtually impossible, the regulations are, indeed, so convoluted that it is equally impossible to determine what flaws exist in the act and what they are or might not be. We look forward to the dialogue between the Secretary and the committee, to give us some assistance in framing these questions in a more understandable way. Given the circumstances, the subcommittee must question whether the Department has been actively seeking to implement the statute or whether there have been efforts to subvert the statute through the backdoor.

We hope that the Secretary, again, will be able to assure us that this is not the case.

One way or other, full implementation of this important public health initiative must go forward and must go forward quickly with meaningful and protective standards, not smoke and mirrors.

The subcommittee will continue its work to see that clinical laboratories provide accurate test data to patients, and it expects a

more expert and aggressive effort from the administration on these matters than it has seen to date.

The Chair now recognizes my good friend from Virginia, Mr. Bliley, for an opening statement.

Mr. BLILEY. Thank you, Mr. Chairman, and thank you for your kind words.

This subcommittee is committed to ensuring that Americans have access to the best of medical care. This means that not only must we encourage technological advances to continue and improve, but we must also work to ensure that those individuals providing medical care are adequately trained.

With this in mind, Congress enacted the Clinical Laboratory Improvement Amendments of 1988, which was an ambitious move forward. Some 200,000 previously unregulated laboratories now come under the watchful eye of the Federal Government. In retrospect, perhaps Congress was too ambitious in its lofty goals and a little unrealistic in some of the timetables it set. The length of time of the rulemaking process was the subject of a hearing before this subcommittee last year. We are here today to hear from Secretary Sullivan about the rule that was published on February 28th, as well as to get some insight from him as to how the process worked or, in some cases, didn't work.

Mr. Chairman, I want to commend the Secretary for his efforts in tackling this difficult and time-consuming task. The scope of the project was vast, but I believe that the Secretary and the Department has taken great pains to get the job done as quickly as possible, given the constraints that he faced.

Mr. Secretary, I welcome you to this hearing, and I look forward to your testimony.

Mr. DINGELL. The Chair recognizes the distinguished gentleman from Georgia, Dr. Rowland.

Mr. ROWLAND. Thank you very much, Mr. Chairman.

Dr. Sullivan, welcome today. It is really good to see you again and my other good friends there at the witness table.

Mr. Chairman, I have long felt and still feel that, frequently, government agencies develop regulations in a vacuum, and I think that is what has happened with HCFA and why we find ourselves in the difficult situation that we are in now insofar as CLIA is concerned.

The agencies do not ask for assistance or advice from those people who would be most directly affected, and I think that may be one of the problems why these regulations have not been developed.

Dr. Sullivan, I want to thank you for the appointment of the members to the panel that we passed about a 1½ years ago that will work with HCFA to provide them some information and assistance in developing regulations.

I think that is one of the big problems that we have, that there is no communication between some of the people at HCFA that are charged with the responsibility of developing these regulations and the people that would be affected.

What this legislation was intended to do was to provide some quality, accurate lab results for patients, so that they could be treated in the manner in which they should be treated, and the

fact that it has not come to fruition at this point certainly does not speak well for what has taken place.

So, I look forward to your testimony regarding what can be done to move forward to put these regulations in place, so that we do not continue to hear the outcry from those people around the country who provide the care, who have been thoroughly confused by what has taken place so far.

Thank you very much for being here.

Mr. Chairman, I yield back the balance of my time.

Mr. DINGELL. The Chair thanks the gentleman.

Mr. Secretary, we are happy to welcome you to the committee.

The Chair notes that all witnesses appearing before the committee testify under oath. Do you have any objection to doing so?

Secretary SULLIVAN. No objection.

Mr. DINGELL. Do any of your associates, Dr. Mason, Dr. Roper, Mr. Toby, Mr. Hays?

[Chorus of noes.]

Mr. DINGELL. Very well, gentlemen.

It is your right, if you so chose, to be advised by counsel if you appear under oath. Do any of you desire to be advised by counsel during your appearance here?

Mr. SULLIVAN. I have no objection.

Mr. DINGELL. Very good.

Then, for your information, copies of the rules of the committee, the subcommittee, the House are there in the red-and the orange-covered books.

Mr. Secretary, if you have no objection, then, to testifying under oath, if you and your associates would please each rise and raise your right hand.

[Witnesses sworn.]

Mr. DINGELL. Gentlemen, you may each consider yourself under oath.

Mr. Secretary and gentlemen, we will recognize you now for such statement as you choose to give the committee.

STATEMENT OF HON. LOUIS W. SULLIVAN, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY WILLIAM TOBY, ACTING ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION; JAMES O. MASON, ASSISTANT SECRETARY, PUBLIC HEALTH SERVICE; AND WILLIAM L. ROPER, ADMINISTRATOR, CENTERS FOR DISEASE CONTROL

Secretary SULLIVAN. Thank you, Mr. Chairman and Dr. Rowland.

I am accompanied today by representatives of the Health Care Financing Administration, to my left, Mr. William Toby, the Acting Administrator of HCFA, and his deputy, to his left, Mr. Louie Hays; also, representatives of the Public Health Service, to my immediate right, Dr. James Mason, our Assistant Secretary for the Public Health Service, and to his right, Dr. William Roper, the Administrator for the Centers for Disease Control.

I am here to respond to the committee's request for testimony on the clinical laboratory standards program, for why my Department has responsibility.

This program, enacted in the 1960's, stands at an important crossroads as it prepares for the challenges of adapting to a very different health-care dynamic of the 1990's.

This is a challenge that I believe my Department has met, in consultation with the Congress and the industry, by completing the first significant update of Federal laboratory standards in 25 years.

Our two fundamental goals for this program are to achieve high-quality reliable laboratory testing and to preserve reasonable access to these services for patients.

I am confident that we are meeting these goals without placing excessive or costly requirements on our Nation's laboratories and without stifling that technological innovation that is associated with the finest high quality health care system in the world.

My Department has had nearly 25 years of experience in setting standards for approximately 13,000 independent and hospital laboratories, where Medicare and Medicaid patients are tested or where interstate shipment of specimens are accepted.

Since we first began this process, we have witnessed significant technological advances that have changed the scope and magnitude of our laboratory capacities as well as the site and practice of laboratory procedures.

Today, it is commonplace for a physician's office to perform laboratory tests that were once performed only in more sophisticated sites.

With the passage of the Clinical Laboratory Improvement Amendments of 1988, the scope of the Department's responsibilities changed dramatically. CLIA 1988 vastly expanded the reach of Federal regulation to all laboratory testing sites, approximately 200,000 in number ranging from physicians' offices and very small public health clinics to large commercial laboratories processing millions of tests.

The majority of these had never before been subject to Federal regulation and oversight. In addition, the basic premise of the standards changed, so now standards are based on the complexity of the test rather than the site as was the case previously.

This approach made sense and seemed in concept straightforward to implement. In practice, it proved extremely challenging to translate into a fair and workable regulatory program.

The complexity of this task becomes quite obvious from one glance at the size of this regulation. Here under my right hand, Mr. Chairman, is the regulation, 1,600 pages of regulations, now the record for my Department in terms of the size the regulation required to implement this law passed by the Congress.

Our task indeed was truly monumental. Let me discuss the process involved to get us where we are today.

By the way, I don't know how many trees were felled to make copies of this to implement this regulation.

Even before CLIA passed, we had begun to update the standards for the laboratories regulated by the Department as well as also establishing new cytology standards. These new standards were issued as a proposed rule. After CLIA passed, the cytology standards were revised to be consistent with the new law and we were able to quickly issue these new standards in final.

We worked to develop the remaining laboratory standards, and that work was divided among HCFA, CDC and the Food and Drug Administration. We gathered and analyzed information about laboratory standards and State licensure laws in effect across the country.

We initiated plans to construct the three-level complexity model, including assigning the more than 10,000 tests to the appropriate levels.

We weighed the conflicting scientific views on the complexity of many of the tests. We considered which tests should be waived from review because of their lack of complexity.

In addition, we began development of personnel standards that balanced the capabilities and the availability of personnel for small laboratories with those of large sophisticated laboratories.

Early in the process, HCFA held a major symposium to solicit ideas about how best to regulate the extensive range of laboratory capabilities now under CLIA. Consultation with outside experts continued on the complexity model. We began to build internal capacity to administer this program, including computer and operational systems for oversight and monitoring.

We issued a proposed rule in May 1990 with 90 days for public comments. In response, we received approximately 60,000 comments. While the volume of response was staggering, the comments were unparalleled in their thoughtfulness and their helpfulness. The medical and laboratory communities gave us invaluable insight into how to craft the final rule to accommodate the wide range of laboratory capabilities, the varied personnel skills, and the diverse settings.

An interagency effort carried out a systematic process to categorize, computerize and extensively analyze the comments over the next 6 months. We devoted 5 months to considering the options and scientifically supportable alternatives. We assembled internal panels of experts and sought the input of additional outside expert opinion. On February 29th of this year, we issued the final rules.

Because of my keen interest in maintaining a dialogue with the public about this issue, I insisted that we invite additional formal public comment. To keep the dialogue open, we will continue to meet with professional societies about implementing the regulations.

Additionally, I established a Clinical Laboratory Improvement Advisory Committee that will help us assess the need for future change. I think it is reasonable for us to expect, due to the complexity and the scope of the regulations, that actual field experience will point to areas needing refinement. We can and will be responsive to the need for change.

In short, we have successfully completed this highly complicated and challenging task to accomplish the following: to develop one set of rules that would assure accurate testing in approximately 200,000 diverse sites; to assure that the standards are adequate and workable for the 10,000 laboratory test methods being used today; and to develop rules flexible enough to cover the hundreds of new tests being developed each year without unduly impeding medical technological advances.

I believe the final CLIA standards achieve the balance between being appropriately flexible to accommodate diversity, while also ensuring safety and accuracy.

That we were able to achieve these goals is due largely to the unrelenting dedication and the superb capabilities of individuals in HCFA and the Public Health Service. This was interagency team work at its best. The Public Health Service's Centers for Disease Control and the Food and Drug Administration provided leadership and creativity to resolve literally thousands of scientific and medical issues. Additionally, the Health Care Financing Administration is undertaking the most expansive enforcement effort ever attempted by this Department and the first user fee collection schedule ever mounted on such a wide scale.

I want to conclude by stating my firm belief that these regulations represent an improvement to our health care system. Our citizens are better off today then they were, and tomorrow, with the experience we gain, will be better off than today. We want this program to be successful and to assure patients and providers that laboratory performance will be of the highest quality. I am hopeful that your hearing today will contribute to that dialogue.

Thank you, Mr. Chairman.

Mr. DINGELL. Doctor Sullivan, Thank you.

Mr. Hays, Mr. Toby, Dr. Mason, Dr. Roper, any additional comments?

[No response.]

Mr. DINGELL. Gentlemen, very well. Then the Chair will commence recognizing members, commencing with the gentleman from Virginia, Mr. Bliley.

Mr. BLILEY. Thank you, Mr. Chairman.

Mr. Secretary, approximately how many laboratories were regulated prior to the enactment of CLIA 1988?

Secretary SULLIVAN. Some 14,000 approximately, Mr. Bliley, in hospitals and independent laboratories as well.

Mr. BLILEY. And how many laboratories are now regulated subsequent to the enactment of CLIA?

Secretary SULLIVAN. Some 200,000, Mr. Chairman, more than a 10-fold, a virtually 15-fold increase in the number of laboratories.

Mr. BLILEY. Can you tell us how the complexity of advancing technology changed the scope of laboratory testing?

Secretary SULLIVAN. Yes. There have been many changes, Mr. Bliley. First of all, due to technological advances, and this includes advances in development of equipment, a number of tests that were formerly only available in sophisticated laboratories are now available or potentially available in physicians' offices.

Our ability for diagnosis obviously has expanded and has become more acute with the development of technology, and we have—many fields in laboratory medicine have improved our ability for early diagnosis of a variety of fields. So in other words, the field has grown expedentially in our capability as well as in the accuracy of the tests available due to improved methodology and improved instrumentation.

Mr. BLILEY. Well, in addition to the greatly increased number of regulated entities, am I correct in saying that CLIA 1988 necessi-

tated the development of an entire new methodology for regulating laboratory tests?

Secretary SULLIVAN. Well, yes. This has indeed given a tremendous expansion of our responsibilities and our capabilities for laboratory regulation, so that, indeed, what we have had to put in place first of all is a cataloging of those laboratories that exist; second, an analysis of the tests, the more than 10,000 different laboratory tests that are available; and then an analysis of those tests to see which fit the complexity model that we developed, which would be appropriate for different settings—the doctor's office, the small laboratory, the large laboratory.

Mr. BLILEY. Well, how much, if any, additional funding did you receive for the implementation of CLIA 1988?

Secretary SULLIVAN. Approximately $150,000, Mr. Bliley, for the completion of these studies.

Mr. BLILEY. Was that adequate?

Secretary SULLIVAN. No. I think that we have been under an enormous financial burden of that size appropriation.

Mr. BLILEY. A number of studies were mandated by CLIA 1988. These studies, if I remember, were to be funded by user fees. Were these studies ever done?

Secretary SULLIVAN. No, Mr. Bliley. Those studies were not done.

Mr. BLILEY. Why not?

Secretary SULLIVAN. Because we were never given the authority for the collection of the user fees and, therefore, the funding for that was not available to us.

Mr. BLILEY. Who didn't provide the authority for the funding for the user fees?

Secretary SULLIVAN. We did not receive that approval from the Congress, Mr. Bliley.

Mr. BLILEY. Was it the Congress or the OMB?

Secretary SULLIVAN. I believe it was the Congress. Let me consult with my colleagues.

Mr. TOBY. This is all user fees. Mr. Bliley, the program is self-funding, and the user fee is——

Mr. BLILEY. I understand that part. I just want to know who blocked the user fees, was it the Congress or was it the administration?

Secretary SULLIVAN. We will be happy to get that. We believe it was the Congress, but if there is any doubt, we will certainly review our records, and be sure.

Mr. BLILEY. I am sure the chairman will keep the record open.

Secretary SULLIVAN. Fine.

Mr. DINGELL. The Chair will keep the record open.

[A response was not received by the committee at the time of printing.]

Mr. BLILEY. What are the costs of the laboratories for these user fees?

Secretary SULLIVAN. It varies according to the size of the laboratory, but it ranges from $300 for the smallest, but up to, I believe, $3,100 for the large sophisticated laboratories.

Mr. BLILEY. When you say large and sophisticated, what are we talking about, is it based on a number of people they hire or is it based on a volume of business that they do?

Secretary SULLIVAN. It is based on the volume and the complexity of the tests that they do. That, of course, is in addition to a registration fee that the laboratories had to pay initially to become registered, and that was between $100 to $600 that was required.

Mr. BLILEY. At our hearing last year, Dr. Wilensky testified that the time table in the statute was simply unrealistic, do you agree with Dr. Wilensky on that?

Secretary SULLIVAN. Yes, Mr. Bliley. Indeed, it was unrealistic because we are talking about a very complex, sophisticated process that we were called upon to mount, in addition to simply the manpower requirements, the manhours needed to actually put this in place.

Mr. BLILEY. I understand that your Department has sought to encourage technological advances. Could you tell us how that was done?

Secretary SULLIVAN. What we tried to do, Mr. Bliley, was to balance the benefits from the proposed tests, again, such things as its accuracy and its utility in clinical medicine.

Mr. BLILEY. In other words, you set up a cost/benefit ratio for each of these things?

Secretary SULLIVAN. Yes.

Mr. BLILEY. To see if the benefit justified the cost, and vice versa?

Secretary SULLIVAN. Exactly.

Mr. BLILEY. Very good.

Thank you, Mr. Chairman. I may ask some additional questions later, but that will suffice for this round.

Mr. DINGELL. The Chair will be happy to recognize the gentleman in the appropriate fashion.

It is time for the gentleman from Georgia.

Mr. ROWLAND. Thank you, Mr. Chairman.

Dr. Sullivan, did you say those were the regulations there? Who do those regulations go to?

Secretary SULLIVAN. These are the regulations that were developed in response to the legislation by my Department to implement the CLIA law.

Mr. ROWLAND. Who gets those regulations?

Secretary SULLIVAN. Of course, these are published in the Federal Register, and they are available to all laboratories, and the general public for anyone who wishes a copy.

Mr. ROWLAND. That is awesome. If I had to look at all of that to try to figure out what to do, I would probably just close my lab. I wouldn't try to pursue that any further.

Secretary SULLIVAN. Mr. Rowland, I would just point out, that is, frankly, one of the reasons we received 60,000 comments from the field. In addition to those 60,000, I can tell you that, particularly during the years 1989 and 1990, virtually everywhere I travelled, visiting hospitals in large cities or in rural areas, talking with physicians, there were many problems that they saw with the law as it was passed.

They really boiled down to a few items. One is the fact that their fear that this new law would really make unavailable tests for their patients, and this is particularly in rural areas, that formerly they had available under the laws. That, they pointed out, would

actually not only be an inconvenience, but would add to the cost of medical care because those tests would have to be sent off elsewhere. The patient could not get an answer on that day. There would have to be a second visit with that patient, and the counselling, and medical decisions that would result therefrom.

So those were the kinds of concerns that were expressed to me both in the written comments as well as in the many, many personal comments I received as far away as Alaska, South Carolina, the State of Washington, or what-have-you. There was widespread concern about that.

Mr. ROWLAND. I heard from many physicians, too, as I am sure you did, and I know you worked hard to try to address those concerns. I wonder, would it not have been helpful in writing these regulations if there had been some communication with the people in HCFA, and the people who are going to be affected, and with the people in the Congress, so that all of this apparent confusion, which is what it was told to me as being, would have been avoided?

Secretary SULLIVAN. Mr. Rowland, I believe we actually did do extensive consultation with people in the field, both as we travelled around the country as well as having individuals come in to the Department. I think my colleagues in HCFA might want to add to that, because I believe that is a misperception of what was the case.

Mr. TOBY. I can tell you that HCFA, in regards to this process, met with a lot of professional groups, and I might tell you, Mr. Rowland, we met with a lot of physician groups. We met, in fact, with laboratory experts. We tried to make this process as inclusive as possible within the constraints.

Mr. ROWLAND. Before any regulations were written?

Mr. TOBY. That's right.

Mr. ROWLAND. Let me ask you this, with reference to the registering of laboratories to determine where testing is being done and who is doing it, has the Department issued its final regulations to register labs?

Do we know where the labs are at this point?

Mr. TOBY. We have issued the final reg, and we also have undertaken a survey to determine exactly how many there are. The survey information is coming in, but we have found, for the most part, that it has been a very, very difficult process of gathering that information. We have contacted over 600,000 entities just to find out how many there are in the country.

Mr. ROWLAND. Recent media reports suggest that many of the registration forms hadn't been sent out yet, and that you hope to have them all mailed by early in May. Is that right, there are still some registration forms that need to go out?

Mr. TOBY. I think you are talking about the bill that would go out for the registration fee. That will go out on May 1, and we expect to get that back around June 1.

Mr. ROWLAND. I am talking about registration forms for the laboratories themselves, those labs that will become registered?

Mr. TOBY. That is right, that is going out on May 1, the billing for it. We have been sending out the information at the same time we do the billing.

Mr. ROWLAND. How many people or entities will receive these registration forms, do you have any idea?

Mr. TOBY. At this time, the information is still coming in.

Mr. ROWLAND. We have heard from some labs, State officials and others that the registration form is confusing to fill out, and that it may take weeks to complete it, and that the information generated won't really be usable.

How long do laboratories, wherever they are located, have to fill out these registration forms?

Mr. TOBY. It is actually about a month.

Mr. ROWLAND. How does the Department intend to use the information that the registration forms presumably will generate?

Mr. TOBY. The information, basically, is going to be used to determine, one, it is going to be used for the billing, and also for determining whether or not they will come into the program, actually, they have to be registered in order to under the regulation.

Mr. ROWLAND. How long will it be before the Department has received and analyzed the information accumulated in these forms, how long is it going to take you to get all this information and deal with it?

Mr. TOBY. Well, the program is effective as of October 1, as you know. So we expect to have that information in by then.

Mr. ROWLAND. And you expect to have it analyzed and be able to have it in a form that is usable?

Mr. TOBY. By September, we are ready to go on September 1, actually.

Mr. ROWLAND. Isn't it true that the registration process, and the certificate the lab will receive has completely eliminated any categorization of labs by specialty?

Mr. DINGELL. We have heard, and the gentleman from Georgia has been addressing this question, a continuous complaint from the people in the laboratory community about the complexity of the forms.

We have also heard that the forms are impossible to automate, so that it will be impossible for you to proceed to automate the processing of these forms.

Are either of those statements true?

Mr. TOBY. We have not, in HCFA, heard that. If we had, we would have been working very diligently to ensure that that is not the case.

Mr. DINGELL. But if you receive many thousands of forms which you can't automate, and which are too complex for the people who are going to be submitting the forms and filling them out, we are all going to have a bit of a problem on our hands, are we not?

Mr. TOBY. I will assure you that they will be automated. I can tell you that one of the major thrusts in HCFA, at this stage, is to reduce as much paperwork as possible.

Mr. ROWLAND. Let me go back to the question I was asking about the specialty. Will the legislation reveal the specialty of a lab? For example, will it be doing microbiology or immunology or bacteriology or virology, or whatever? Does the certificate specify?

Mr. TOBY. We will ask for the kinds of and types of tests that will be performed and ownership information about the labs, and

whether or not they are hospital based in terms of the type. That's to kind of—that gives us just about everything we need.

Mr. ROWLAND. Well, then, this is kind of a blanket certificate, I guess, that lets a lab do testing, and you really won't know what kind of testing they have been certified to do from this certificate that's issued to them. Is that an accurate statement or not?

Mr. TOBY. No. We think we are going to know the kind of testing because under the monitoring system, we have to know that to make judgments about whether or not their certificates give them the right to perform the test they're doing and the kind of quality work they're doing. We have to know that; otherwise, we can't do our job in terms of what Congress has asked us to do.

Mr. ROWLAND. The final regulations indicate that you have completed all of the inspections that are going to be necessary within the next 2 years. Is that correct?

Mr. TOBY. That's correct, starting on September 1. It's a 2-year cycle.

Mr. ROWLAND. OK. So in that additional 2-year period, we still don't know how accurate the testing is at virtually any lab. There's another 2-year period that we won't know.

Mr. TOBY. Well, some of them we're going to inspect almost immediately because we are phasing in the inspection.

Mr. ROWLAND. But they've got to have an adjudication from you about whether or not they are in compliance.

Mr. TOBY. My colleague, Dr. Mason, will add to that.

Mr. MASON. Dr. Rowland, with the registration, we will then have a good idea about whether this is a general laboratory, a specialty laboratory, or even a sub-specialty laboratory. We'll know the types of test they are performing or wish to perform and volume.

Initially, there will be issued simply a certificate of registration, and that certificate of registration will carry with it an expectation that those laboratories will come in compliance with all of the requirements of CLIA 1988 that go into effect on the 1st of September.

Now, some of those will be phased in over a period of time, some of the personnel requirements, some of the quality control requirements, and proficiency testing requirements. But each laboratory will be on record that they must meet by September 1 all of the requirements that go into effect on the 1st of September.

Now, when you deal with 200,000 laboratories, it's obvious that the Health Care Financing Administration is going to have to employ and train, and then there is another regulation that is being published within another day or two which will provide deeming to private non-profit organizations who meet the requirements of Health Care Financing Administration so that they can inspect in lieu of the Federal Government. Also, States that meet certain requirements will be able to make inspections as well.

But it's going to take approximately 2 years through the deeming the State organizations that meet the requirements plus the Federal Government to get to those laboratories.

But the laboratories, although they probably will be told in advance of the inspection, they don't know whether it's going to occur during the first 6 months or the last 6 months. When those inspec-

tors come, they will expect that there will be certain compliance, and where they find lack of compliance, a plan will have to be put into effect to bring them rapidly into compliance, and in those cases where serious problems are uncovered, then action would have to be taken even during that 2-year period.

Mr. ROWLAND. I guess there's going to be a period——

Mr. DINGELL. Will the gentleman yield?

Mr. ROWLAND. I yield.

Mr. DINGELL. I thank the gentleman.

Dr. Mason, the laboratory universe, or, rather, that which will be regulated on September 1, that will be basically the labs which were previously regulated under the Department's practices, will it not?

Mr. MASON. It will include the 12,000 to 14,000 that are already being regulated under CLIA 1967 and, of course, they will be expected to continue, and even the proficiency testing won't be phased in with them. They've got to ongoingly meet all of the requirements of CLIA 1988. It's the laboratories that have never come under Federal regulation that will be inspected during that initial 2-year period and where there will be a phase-in.

Mr. DINGELL. But your September 1 universe will be labs which were previously regulated, and then in the following period of 2 years, you indicate that you'll be bringing in others? Is that what you're telling me?

Mr. MASON. No. The certificate of registration will be issued to all of the laboratories on the 1st of September, and that's why we must rapidly get these forms in that Mr. Toby was talking about, get them onto the computer so that they can be handled, so that the inspection process can be scheduled. But they will be phased in over the 2-year period, but be expecting—we will expect that they will meet all of the criteria that go into effect on the 1st of September. No sanctions for certain things will be rendered against them if they are in deficiency except for those things that are life-threatening—that's that threaten the safety of people.

Mr. DINGELL. Thank you, Doctor.

Mr. ROWLAND. One other question, Mr. Chairman. I have a form here, I believe, that is to be filled out. Is there any way that this form can be scanned so that it can be immediately put into the system or will each one of these forms received then have to be manually put into the system by someone sitting there with a keyboard and putting in information?

Mr. TOBY. Actually, we have a contractor who actually—who is going to do that for us.

Mr. ROWLAND. Yes. Well, is the contractor going to have to manually put this information in and——

Mr. TOBY. It will have to be keyed in, yes.

Mr. ROWLAND. Yes. That's going to be really time consuming, isn't it? Wouldn't it be much better if you had some sort of form that you could put through a scanner that could immediately put that information in? I'm just asking from a standpoint——

Mr. TOBY. Well, I imagine at some point we would be able to do that, Mr. Rowland. I must tell you, this is a very complicated undertaking, and I'm sure we can make improvements in the process as it goes forward. But in the history of regulation making, this is

perhaps one of the most complicated and complex. We'll learn as we go along.

Mr. ROWLAND. Thank you, Dr. Toby and Dr. Sullivan. I yield back the balance of my time.

Mr. DINGELL. The time of the gentleman has expired.

The gentleman from Oregon.

Mr. WYDEN. Thank you, Mr. Chairman.

Dr. Sullivan, welcome, and let me use this as an opportunity to also thank you personally, and Dr. Roper, for the excellent help that you have given me in developing legislation on the fertility clinics. That's a bill that, as you know, has already gotten out of committee and it's ready for the floor. The conversations that you've had with me and the help that Dr. Roper has given has been extremely helpful and I want to express my appreciation to you.

As I think the staff indicated, and Chairman Dingell is aware of this as well, I think that any Member of Congress from the State of Oregon who did not ask about the status of Oregon's Medicaid waiver when he had the Secretary of Health and Human Services here this afternoon would probably be tarred and feathered, and I think we indicated that to your staff. I just wanted to ask one question and then seriously move on to the matter of CLIA.

As I'm sure you're aware, the Office of Technology Assessment has done a report here very recently that has indicated that for the additional enrollees in Medicaid, the Oregon plan would be unambiguously good was the characterization of OTA, and OTA found that the Oregon Medicaid waiver would in no way harm the existing Medicaid population.

My question to you, Dr. Sullivan, is really two-fold. There is such strong bipartisan support for the waiver, both at home in Oregon and here in the Congress. What our State would like to know is, first, are you aware of any outstanding issues that Oregon still must address to get a decision from the Department with respect to a waiver, and second, when might we expect a decision pro or con on our waiver?

I appreciate your consideration. Chairman Dingell was gracious to allow me to ask one question so at least I could go home without getting killed by my constituents, and, with your indulgence, your thoughts on that.

Secretary SULLIVAN. Thank you, Mr. Wyden.

Let me respond to you in this way. First of all, I just responded to a similar question before the National Press Club that went out over NPR, so I think I've already spoken to some of your constituents earlier today.

Mr. WYDEN. I missed that.

Secretary SULLIVAN. But to also respond to it here, we have requested—as you know, among our guidelines for approval of waivers is that the application has to show Federal budget neutrality impact of the program as well as the capability of mounting an evaluation of the program.

We requested, when we received the proposal from your colleagues in Oregon and reviewed it, we requested some additional information concerning the issue of budget neutrality. We did receive approximately 3 weeks ago a letter from them in response to

that. We are in the process of analyzing that response and we may need to have some more detailed information from them. But my staff is in constant contact with the officials in Oregon.

I stated earlier this year that we were committed to having an answer on the Oregon waiver in the spring; so we clearly are working towards getting an answer for you. We don't have that yet, but because spring goes until June 20th, we have a few days yet to meet that deadline for getting that answer.

But we are very much aware and indeed you and your colleagues from Oregon here in the Congress have made us very much aware of that, as well as discussions with Dr. Kitzhauber and the legislature in Oregon and your Governor and others.

Mr. WYDEN. Well, we will not quibble with the Department over the definition of when spring ends, Dr. Sullivan, but obviously it is essential that if Oregon is to move forward with this, a decision be forthcoming. I want to express my desire to cooperate with the Department and the desire of the State to get all necessary information, because it seems to me that the OTA report took the legs out from the critics who said that Oregon's plan wouldn't work and wouldn't make a difference for the poor. I thank you for the answer, and I want to thank the chairman for allowing me to deviate from today's topic for that one question.

Let me ask one question also dealing with the CLIA matter at hand, because it deals with a concrete case—cholesterol testing that I think raises some issues about where we are headed.

Now, Doctor, a couple of months ago, a National Institute of Health panel recommended broader cholesterol testing to identify those at risk from coronary heart disease. This involved the panel recommendation from the National Heart, Lung and Blood Institute, a recommendation involving additional testing for the so-called good cholesterol, the HDL cholesterol.

Do you agree with this recommendation that has been made by this panel of the National Heart, Lung and Blood Institute, and does the Department intend to push for implementing their recommendation?

Secretary SULLIVAN. Thank you, Mr. Wyden.

Let me first say that indeed, we are quite familiar with that recommendation, but I would begin by saying this is a recommendation from NIH; this is not a departmental recommendation. This is a result of a consensus conference which, as you know, involves a number of scientists from the field who come in to give us their best advice.

But the second part of my answer is that this recommendation as I understand it is really for those instances where it is felt that there is specific reason for that further testing to be done as opposed to applying this across the board for a general screening examination. The measurement of high density lipoproteins is a difficult one with a certain problem of accuracy.

We believe that those tests are best done in conjunction with other tests or signs to suggest some potential problems are there, and not simply as a screening test. So we don't anticipate implementing them broadly for screening.

Mr. WYDEN. Well, I think I would share your view, Dr. Sullivan, because if you were to implement it for everybody, you'd be talking

about 100 million according to what the panel has estimated. So would it be fair to say that you would believe that the recommendation at this time warrants approval if there was the particular kind of cut-off as you outlined it for that certain group of individuals?

Secretary SULLIVAN. Yes. This is a test that we believe should be done really in consultation upon recommendation of the patient's physician, who would take into account other factors that would lead to the decision that this test would be of value, yes.

Mr. WYDEN. The reason I ask this is, as you know, Chairman Dingell and I were digging into this issue of clinical labs back in 1989, and on my Small Business Committee in conjunction with Chairman Dingell, we looked at the cholesterol test specifically and found extraordinarily wide variation, I mean variations that were so wide that they would in effect affect the judgment that you just outlined as to whether or not you treat an individual for these high cholesterol conditions.

What steps would you see the Department take to ensure that the right people got the test and that the test was done with a fair degree of accuracy so we could avoid the problems that we saw back in 1989?

Secretary SULLIVAN. Yes. Well, first of all, as I indicated, this really should be a test that is done not in isolation, but in conjunction with other measures that the physician would be involved in.

Second, certainly for those laboratories that do these tests, we would want to be sure that they have the appropriate standards in place to be sure about the accuracy of the tests. This is one of those tests that does require a certain level of proficiency for it to be of value.

Mr. WYDEN. Well, again, I share your view, and it's because I share your view that I'm concerned about where we're headed. Our understanding is that your regulations state that laboratories must get results within 10 percent of their actual value for total cholesterol and within 30 percent for the HDL matter specifically.

NIH on the other hand is now recommending a lower total—I believe 3 to 5 percent on total cholesterol and 6 percent on HDL.

Now, clearly we want to have the kind of interagency cooperation that you have talked about. How is the difference between these two standards going to be reconciled or are we going to start down the road in an area where there's enormous public interest, the matter of cholesterol testing, with two different determinations, creating a situation where you and the good Dr. Roper are up before Chairman Dingell again with another stack of regs this high from yours and that high from NIH. I would be interested in your thoughts about how we reconcile the difference there between the two.

Secretary SULLIVAN. I'm going to have my colleagues from the Public Health Service comment, but let me indicate that first of all, we are providing funds to the States for them to work with the laboratories in their States, and we're providing technical assistance to ensure that the best possible accuracy in this test is available in those laboratories that do it.

On the other issue of the reconciliation between two different recommendations, I'll have Dr. Mason comment.

Mr. MASON. I think this is an excellent question. Let me just say that I think the purpose of the consensus development conference has been a bit misunderstood. The reason that NIH brought together this independent panel of experts is simply because there has been so much controversy and so much disagreement. Their recommendation was not that every man, woman and child be screened for cholesterol and high-density lipoprotein; their recommendation was that when it is used, that HDL should be combined with cholesterol, and that the measurement should be done in an area where it can be done accurately, not in a shopping mall or a trailer from a finger stick.

So their recommendation specifically was hitting at some of the abuses that have taken place, and that brings this right back around to CLIA 1988, because under CLIA 1988, both cholesterol and high-density lipoprotein, depending upon the methodology that's being used, will either be a moderate or high complexity determination, and it will begin to spell out under what standards, quality control, and who can do these determinations, so we won't get this shopping mall type of finger stick.

It isn't just that we have a good test; there also needs to be counseling between a physician and the patient so that they know what those levels do.

Now, in addition, getting back to the standardization of levels and what's happening there, there's a lot going on at both NIH and CDC, and I think CDC is doing some exciting things to make sure that we have better capacity for accurate testing out in the field.

Dr. Roper.

Mr. ROPER. I would just add to that that making sure that the right value is considered is one of the things that we do in sorting out the matter between our two agencies, NIH and CDC.

In addition to that, CDC working with State health departments is assisting them in putting in place the capacity to do these determinations in the public sector. But the most important point I'd make finally is testing for cholesterol, as Dr. Mason has just said, is covered under CLIA 1988 with all of the requirements that the Secretary has outlined to you, and over time, the Secretary has built into CLIA 1988 an advisory committee that will make sure that we are at the state of the art in applying whatever regulatory effort needs to be.

Mr. WYDEN. Dr. Sullivan, we have a vote on the floor, and maybe, with Chairman Dingell's indulgence, we can pursue this in a few more minutes. I share your views, and I think my only concern is that if we really want to reign in those kind of abusive practices that Dr. Mason is talking about—and clearly the Department does, and, in fact, I had a hearing with Mr. Kusserow on the shopping malls, and you all assisted us on that as well—we 're going to have to have some tools to have consumer protection clearly stated and clearly understood, or else people are going to run around shopping malls, and they'll say, "well, the Government has this standard" when in fact it's another standard, and they'll be able to cite two different approaches, such as the situation that we're in now with NIH going one way and you all going another.

I very much want to work with you so that we do get a standardized approach that's clearly understood, and that probably does

more to shut down the abusive practices of people running around malls and the like than anything else. Maybe after the vote we'll get a chance for some other questions.

Thank you, Mr. Chairman.

Mr. DINGELL. The time of the gentleman has expired. The Chair is going to recess while we go to vote. We will return as quickly as we can. The Chair estimates that we will be back here in about 25 minutes to the next hour. The subcommittee will stand in recess.

[Brief recess.]

Mr. DINGELL. The subcommittee will come to order. The Chair recognizes the gentleman from Oregon for questions.

Mr. WYDEN. Mr. Chairman, I only had one other question at this point and perhaps could get some a bit later.

Dr. Sullivan, on the cholesterol matter, when would you anticipate the differences between the approach that you all are taking and NIH being resolved so that there would be one clear standard and we could move to address the issues that Dr. Mason was talking about about making sure there were fewer of these abuses in the malls and the like, because I think that that is a clear problem and we all agree on it.

Secretary SULLIVAN. Yes, Mr. Wyden. Let me say that, first of all, NIH is a very integral part of our Department, and we really do look to NIH, which is a biomedical research organization, to really give us the state of the art for a number of things in medicine.

But the way the consensus conferences at NIH work is they will consult the field widely with experts to get their consensus, but in so doing or holding such conferences, this doesn't mean that NIH itself formally endorses the recommendations of the consensus conference.

We will be working with NIH in an ongoing way to indeed come up with the best most practical approach to measuring cholesterol and lipoproteins in a practical way that's suitable for widespread use.

Mr. WYDEN. Dr. Sullivan, maybe I'll follow it up in just one other area very briefly. Given the fact that NIH has made this recommendation, and let us set aside the difference between your Department and theirs just for a moment. Would you anticipate that there would be a sharp spike in additional and lucrative testing in this area?

Secretary SULLIVAN. I would not, Mr. Wyden. Again, let me just say that NIH is part of my Department. They are really a part of us, and we clearly—we are not bothered by the fact that they have come up with some recommendations there that might be somewhat at variance with what we are doing with our activities involving HCFA, FDA and CDC, because they by nature, being a research organization, would always be pushing the envelope in terms of testing.

But answering your specific question, no, we would not anticipate that there would be an industry spawned for such testing because of our recommendation that such testing should be done in consultation with the physician, taking other clinical data into account concerning particular patients.

In other words, we do not believe that these laboratory tests by themselves, standing alone, are really to be taken without the other clinical information about the patient. So we are recommending that they would be used in conjunction with other clinical information about the patient.

Mr. WYDEN. I think what concerns me, I've got a story from the Washington Post, February 29, 1992, big headline: Panel Suggests Broader Test For Detecting Heart Disease. It seems to me what's going to happen is people are going to see those headlines and they are going to rush out to have these tests, and I would see a very sharp spike upward in terms of additional tests and lucrative tests. Is that——

Secretary SULLIVAN. I'm going to invite my colleague, Dr. Mason, to comment on that, Mr. Wyden.

Mr. MASON. Cholesterol tests are already so broadly used in the United States as well as HDL. I know since 1982, I've had about a bi-annual physical, and each time, they've done cholesterol and HDL.

This isn't a new process and the purpose of the consensus conference was to try to get some consensus in the scientific and medical community about what should be done. What they basically said, as the Secretary has indicated, is that if you're going to do a cholesterol in evaluating one's coronary heart disease risk, then it ought to be coupled with HDL, but it ought to be done in a proficient laboratory where there is good counseling between the physician and the patient.

Actually, the recommendations of this consensus conference then are going to other parts of the NIH where they will look at them and address this. For example, the Adult Treatment Panel of the National Cholesterol Education Program is looking at their recommendations, and they would have to endorse this as a national type of program before it would even become an NIH recommendation.

Mr. WYDEN. Let me ask this of you, Dr. Mason, on the cost, which again is an area that I'm concerned about. There seems to me to be two issues—the discrepancy in standards and, second, the cost. The data we have indicates that the cost of a total cholesterol test is about $5. HCFA's data from Medicare suggests that between $15 and $20 is the average price for doing both the HDL test and the total cholesterol test, and that sometimes these numbers are much higher.

Now, the panel acknowledged the problem with obtaining accurate HDL test results by recommending that three HDL tests be done. Given again the increase in the amount of money that would be paid for by the test, it seems to me that the results of this recommendation could be paying billions and billions of dollars for tests that might not be accurate, and having the Department's view on how we would protect against that possibility is what's on my mind.

Mr. MASON. Well, let me address that. What the consensus panel really recommended was that you don't use HDL as a basis for therapy until you've repeated it three times. They did not recommend that this be routinely done for anyone that was being evaluated by a physician for their coronary heart disease risk, but they simply said because—they acknowledged what you just said—be-

cause of the variability of this test, a physician would not want to go on then and prescribe a cholesterol lowering drug unless you had repeated that.

They really commented that what the physicians are to prescribe, rather than repeating the test, was that the physician ought to encourage exercise appropriate to the individual, diet, stopping smoking, and the other risk factors before you go into treatment, and you wouldn't need to repeat it three times before you advocated those kinds of behavioral modifications.

So when you read the consensus conference report from beginning to end, I think it is quite balanced.

Mr. WYDEN. I would very much like to work with the Department on this, because it seems to me with newspaper headlines screaming across the paper urging broader tests to detect heart disease, these figures that would indicate certainly a significant increase in the amount of revenue that would be involved in having both of the tests, and certainly a recommendation considering Dr. Mason's comments that in some instances, three HDL tests be done, we could be off into the blue sky spending billions and billions of dollars in a fairly dubious kind of fashion.

So Dr. Sullivan, again, we appreciate your cooperation. This is an area that, in conjunction with Chairman Dingell, that I would like to work because I think that the public is going to flock to these kinds of tests, and resolving the discrepancies, addressing the cost questions are going to be important.

Mr. Chairman, thank you.

Mr. DINGELL. The Chair thanks the gentlemen.

Dr. Sullivan and Dr. Mason, the regs at NIH say that the labs must get results within 10 percent of their actual value for total cholesterol, and within 30 percent for HDL. NIH on the other hand recommends 3 to 5 percent error on total cholesterol and 6 percent error on HDL. What is an acceptable level of error in computing both total and HDL levels?

Mr. MASON. Mr. Dingell, I don't know, and I'd be happy to get that information for you.

Mr. DINGELL. Well, at what point do you run into a situation where you're getting a result which is going to lead the doctor to apply bad therapy or endanger the life or the health of the patient? Obviously at some point, that is going to occur. Does it occur at 10 percent? Does it occur at 30 percent? Does it occur at 3 to 5 percent, or does it occur at 6 percent?

Mr. MASON. That really depends upon the specific test and how precise. What one is really trying to learn is, is this individual's cholesterol or HDL significantly elevated, and do you need to take action based upon that, and one has to be much more familiar with the mechanics of the test than I am to let you know specifically.

Mr. MASON. Doctor, do you have a comment?

Secretary SULLIVAN. Yes, Mr. Dingell. One of the things that I think this particular test illustrates is that the range of normal under the most stringent and sophisticated laboratory tests in the population is quite broad for cholesterol; as you know, it will go from something like 90 up to about 260, 280. It's really sort of like height; you know, some people are 6'6" and they are healthy, and others are 5'6". So it's because of that—that's the first thing as op-

posed to, let's say, a blood hemoglobin level. You don't see that wide range.

But in addition to that, you have the complexity of the test itself. That is why it is recommended that this test not be used alone, that it be used in conjunction with other data and consultation with the patient's physician because it is a more complex test, and there is such a range with it. We are working—and the field is working always to improve the accuracy, you know, of the test.

Mr. DINGELL. Of course, I'm driven to two questions here. The first is, if these are not very accurate and we don't know what the limits are, maybe the test isn't of great value, and if you're going to have to use this test in connection with other things because it really is not good in evaluating, maybe we ought to just do the other things and ignore this test in the first place.

Now, I don't think either of those is a good position, but the harsh fact of the matter is, if we do not have a test which gives reasonably good and accurate results which are subject to being evaluated in a sensible way, then maybe we ought to take a fresh look at whether or not that test is required, whether it should be approved, or whether the testing limits that you would accept are perhaps subject to too many vagaries and too much variation.

Secretary SULLIVAN. Well, clearly, if heart disease were not such a major health problem for our population, I would agree with you. The fact is, as you know, this is the number one cause of death in the United States, and therefore, these tests as well as others are important in our overall assessment.

It so happens that in comparison with the number of other tests that we have, there is this broad range. This doesn't mean that there might not be developed in the future better test methods that don't give such a variation or alternatives that indeed are better.

But even with the limitations of the test's variability, it does have value, but it is because of this variability, of course, that the recommendations have been made that there should be at least three of these tests done before therapeutic decisions are made, you know, on that basis.

Mr. DINGELL. Now, isn't it probable that, regardless of the discrepancies we've been talking about, a great deal of cholesterol testing, including HDL, will be done in the doctor's office and public health screenings? Isn't that a probability we're talking about, gentlemen?

Secretary SULLIVAN. I'll have Dr. Mason respond to that, Mr. Chairman.

Mr. MASON. Mr. Chairman, there is already a lot of cholesterol and HDL and triglyceride and a whole series of cardiovascular screenings that are being carried out, and when the physician can evaluate his patient's family history, when you can talk about behaviors of the patient, whether the individual uses tobacco and other things, then these tests can become very, very useful and helpful, and they can be the basis for pharmaceutical agents or behavior modification.

That's why we strongly disagree with doing this kind of testing in a shopping mall or with a finger stick, which tends to be even more inaccurate. The very reason that this consensus panel was brought together was to comment on an area which really is part

of cutting edge science investigation. We need to have more information. But if we're going to do the tests, and they can be very useful in the physician's evaluation of the patient, then the test ought to be done accurately with the greatest amount of precision possible.

As part of the NIH study, they're talking about how we can get better standards for HDL—we don't have good standards—we can improve methodology, we can improve instrumentation, and that's really what will come from this consensus conference, is greater efforts on the part of researchers to do a better job. You know, we've got to move the envelope so that we have better tests in those areas that will be clinically useful.

Mr. DINGELL. I appreciate that. The New York State lab regulators have told the committee that even in the larger already regulated labs, fully 5 percent can't meet the standards that are set forth by HHS. Is that true or is that not true?

Mr. MASON. Part of the HHS or NIH process is to send to all laboratories that are participating a standard so that they can all try to get—in other words, a laboratory in Washington, D.C., Baltimore, San Francisco, or Los Angeles, would receive from NIH the same standard with the attempt to make the test—the result that you would get the same in all of these communities, and the only action that I know that NIH has taken is to help standardizations around single specimens so that we can begin to get comparability from one laboratory to another. That's the very purpose of the NIH specimens that are being sent out.

Years ago, this was done for cholesterol, when you couldn't even get a valid cholesterol that would compare from one city to another on the same individual, and through sending these standards out throughout the Nation that all the laboratories could use to sight in their chemical test rifle, then everyone began to get the same value wherever they were in the Nation. This is exactly what NIH is trying to do with regard to high-density lipoprotein.

Mr. DINGELL. Of course, the trouble here that I'm trying to confront is that New York State regulators have told us that even in the currently regulated labs, the larger and more important ones, that fully 5 percent can't meet NIH standards at this time. Is that true or is that not true?

Mr. MASON. I don't know.

Mr. DINGELL. Do you have any information that would contradict those findings?

Mr. MASON. No, but we'd be happy to supply that to you.

Mr. DINGELL. Would you check that out for us, please.

Mr. MASON. And I would say that NIH would probably suggest as a standard—in other words, they are looking at what would be optimal. They are not telling State programs what range or value that they have to get. That's what—I would say that New York State ought not to be realistic in what they are expecting from their laboratories. This is what a research laboratory or a top notch clinical laboratory could achieve. That doesn't mean that all the laboratories that New York State is examining and regulating can meet it. And then they have to determine whether the information that's coming out of those laboratories that aren't meeting the standard, it might still be clinically useful. If it's not clinically

useful, then they shouldn't be doing the test if they can't meet that requirement.

Mr. DINGELL. Of course, you have told us that the problems with obtaining accurate HDL tests have led the HHS to start pushing the thesis that there should be three HDL tests done. That means you are buying three tests instead of one, and on Medicaid and Medicare and health insurance, you're paying for two tests that you don't need rather than one which might be useful.

Mr. MASON. Mr. Chairman, again, as the Secretary said, NIH brings outside experts in as parts of panels to look at highly controversial areas. They don't hold consensus conferences where there is agreement. NIH often puts a caveat even when the report of the consensus conference comes out that this does not mean that this recommendation is endorsed by NIH; it simply means this was the recommendation of a group of experts in the field.

Mr. DINGELL. But you are going to be paying out of Medicare and Medicaid moneys. This is going to cost a pile of money. HDL tests are not cheap. Your mechanisms for dealing with it are dietary changes, exercising, ceasing smoking, perhaps cholesterol lowering medications and things of that kind. But here, you are urging three tests rather than one, tests everybody seems to agree aren't coming up with very accurate results.

I recognize that doctors who are very good are going to use a lot of other things to come to a judgment, and they probably need this test, but it seems that this is a major contributing factor to, quite honestly, the kind of policy that drives the rapid escalation in health costs that exists inside the United States.

Mr. MASON. And this group of experts were trying to convey to the doctors of the Nation that if you're going to use HDL as the basis for drug treatment, pharmaceutical treatment of high cholesterol and low HDL, don't do it on the basis of one determination, and I think that is a reasonable recommendation.

If you are going to use that as the basis for your prescribing a drug which also is costly, because of the variation in the test, make sure that the person really has a significantly lowered HDL, and I think that is a reasonable precaution, and doing two more of those tests before treating is much less expensive than unnecessary treatment of someone who doesn't need these costly drugs. So one has to balance one against the other.

Secretary SULLIVAN. Mr. Chairman, if I could add to that.

Mr. DINGELL. Sure.

Secretary SULLIVAN. I just want to emphasize Dr. Mason's last point. The therapeutic decisions that are made to treat individuals for high cholesterol involves long term therapy, so that if you look at the cost of that long term therapy vis-a-vis the cost of doing the second and third test to be sure, we think that it is cost effective, realizing the fact that we don't have an optimal test here that we could simply rely on doing just once. It's because of that variability that that recommendation is made.

Hopefully in the future, we will have improved testing that wouldn't require that, but rather than having decisions made on one test, we think that the recommendation to add in those other tests in the long run is cost effective as to decisions made about implementing therapy in these individuals.

Mr. DINGELL. Of course, Doctor, here we've got tests which we agree are not very accurate, wide swings permitted by the regulations of NIH and HHS, with NIH suggesting rather lower limits on accuracy. I'm not going to say that testing is not important—as a matter of fact, it's very important—but testing which gives you the best possible results is also very important, quite obviously, in terms of saving money.

Doctor, the committee has been concerned about the charges that we hear from time to time within your Department and elsewhere that there are special interest pressures which are asserted on your advisory panels. What measures does the Department employ to guard against potential conflicts of interest on these advisory panels?

Secretary SULLIVAN. We have, Mr. Chairman, a standard inquiry to all individuals who are asked to serve on advisory panels to disclose any real or even potential conflicts of interest. Those have been in place longstanding. This involves any financial interest that they may have in, say, laboratories, or any other interest.

That is reviewed by our departmental staff to assure that there is no such interest, or if there should be a conflict in a narrow area and the committee actually has a much broader mandate for review, that individual, because of his or her expertise, may be invited to serve on that committee, but would not participate in discussions or decisions in that area where there is a conflict.

So we work very hard to be sure that there is no conflict, or if there is a conflict that can be narrowed, then that is done, you know, with that knowledge.

Mr. DINGELL. Your form letter which you submit to the people who would serve on these panels lists amongst other things relevant financial interest, relevant publications, public positions or memberships. I'm curious, would receiving grant funds, travel funds, speaking honoraria, to name a few, be considered by your Department to be financial interests which would affect the judgment or the objectivity of persons who would appear on one of these advisory panels?

Secretary SULLIVAN. I'm not sure if I understand. The——

Mr. DINGELL. I'm just trying to get a definition of what constitutes a conflict of interest here as you might see it.

Secretary SULLIVAN. Yes. If a scientist were invited to give a talk at some institution or what have you, and that person receives travel funds and even—this is in the private sector—or even an honorarium for that, that we would not consider a conflict because that person is actually being reimbursed for out-of-pocket expenses to share his or her knowledge and expertise.

On the other hand, if that person were a scientist who were retained by some organization to give a series of talks around the country with some kind of financial arrangement to pay that individual for services, that's the kind of arrangement that we would want to know about because then that might then raise that level of concern to such that we might then believe that there would be a conflict or a potential conflict, that we would not want that person to serve.

But in the scientific community, we very much value the exchange of information broadly, and therefore the usual process

where scientists are reimbursed for their travel expenses and given an honorarium we feel does not constitute a conflict.

Mr. DINGELL. Doctor, I take it that we both agree that the HDL panel's recommendations were not included in policymaking decisions at the departmental level. Is that correct?

Secretary SULLIVAN. The NIH recommendations?

Mr. DINGELL. Yes. Their recommendations were not included in the policymaking decisions of the Department.

Secretary SULLIVAN. That's correct.

Mr. DINGELL. I'm curious. Is this regular practice? If the panel's recommendations aren't included or considered in the policymaking decisions at the departmental level, what purpose do the recommendations of either the panel serve or for what purpose should we constitute a panel of this sort?

Mr. MASON. Often in a consensus conference, because of the controversy surrounding the particular agenda item, they may even choose people that have a conflict of interest. I think the important thing about the conflict is that it be recognized by everyone there, including the individual, where there is disclosure.

For example, in the consensus development conferences, these are not chartered advisory committees; each person comes to represent himself or herself. When the Department under the Secretary creates a formal advisory committee with a charter—in the case of the National Vaccine Program Advisory committee, we actually put representatives of the pharmaceutical industry on the panel because they provide a point of view that is important to the deliberations that are being carried out by the advisory committee. The same may be true for a consensus conference, where you do want the opinion of someone representing industry.

So I think all of that has to be balanced in terms of getting a full array of opinions with regard to the subject being discussed.

Mr. DINGELL. Thank you.

Mr. Secretary, I'd like to go to the waivered tests question. The final regulations establish three categories of tests based on a complexity model developed by the Centers for Disease Control. There are these categories: One, the waivered tests that are totally unregulated; two, tests of moderate complexity; and three, tests of high complexity.

Now, Mr. Secretary, I'd like to ask about how you determined which tests should fall under the waivered list. The Act specified that waivered tests had to be so simple and so accurate as to render the likelihood of erroneous results negligible.

Now, despite the CDC's original recommendation that no tests could meet that standard, CDC later concluded that eight types of tests did meet that standard. At the last hearing of this subcommittee on this matter, Dr. Roper was unable to explain the change in CDC's recommendations.

Let's discuss a few of these tests here, then.

The Department exempts glucose testing, but our hearing last year saw one of Maryland's top lag regulators come in and explain how three patients had died at a nursing home because of an improperly performed glucose test. The College of American Pathologists and the American Association of Bioanalysts confirmed that

glucose test results ranged from twice the real levels to normal or 50 percent less than normal.

Now, glucose testing was exempted by the Department. Does that mean the results are immaterial, or does that mean that you should revisit the question of these kinds of tests and this testing, referring specifically to glucose tests?

Secretary SULLIVAN. Thank you, Mr. Chairman.

Let me say that generally in terms of the eight tests that were waived, this is the result of broad consultation with the laboratory community and the hospital and physician community that we have come up with that list.

Now, when it comes to glucose testing itself, we are familiar with those reports of adverse reactions, but we would point out that the number of these tests that are done in the country to manage diabetics is indeed in the thousands, so that as we compute the number of adverse reactions here, I think it's like .0003 percent adverse reactions.

We are concerned about those adverse reactions. Some of them have been related to the fact that the instructions that go with the glucose testing have not been what we call user-friendly. The FDA is working with the manufacturers of these test devices in an effort to make sure that those instructions are made as clear and simple and as straightforward as possible.

But we believe that the use of these tests is indeed very important because of the importance of the management of diabetic patients with their blood sugars. Actually—I've been corrected—the number is really in millions than in the thousands.

So while there have been these problems, compared to the magnitude of use, it really has been quite small, but nevertheless, we agree that we want to strive to improve the reliability of the tests and the ease of administration even more to try and reduce those adverse reactions even further.

Mr. DINGELL. Well, let's just go over the history of this. The committee has received testimony saying that the levels that the test show are off by somewhere between showing 50 percent less than they should to double the amount that they should. Three people have died because of this.

Doesn't that tell you that we have a problem here on this particular test, which is a waivered test? You tell us that that's because the instructions coming out with the test kits are not clear enough for testing laboratories to understand. Is it because the manufacturers can't put out a properly done test kit with proper instructions, or is it because the people at the laboratory are not capable of understanding scientific jargon?

Secretary SULLIVAN. Well, Mr. Chairman, these tests are licensed—I believe the ones you are referring to are the ones that are licensed for home use, where there have been the adverse reactions. What we are doing is working with the producers of these tests to be sure that their instructions that they give can be made as easily understood as possible.

In other words, what we have found when there have been problems has been usually the test has not been correctly or appropriately carried out; there has been confusion or misunderstanding of that.

So this is where the FDA is working with the manufacturers to be sure that we have the most clearly understood instructions that we could possibly develop.

Mr. DINGELL. Well, but I see here that you have people who are holding themselves out as capable of affording tests who apparently are not even competent to call up the manufacturer to say, "Your test instructions are not good. What test instructions should we really follow?"

Let me talk about another of your agencies here, Doctor. The Food and Drug Administration has received over 3,200 reports which allege that 17 deaths and 871 injuries resulted from an inaccurate glucose tests.

Now, admittedly there are many thousands of tests performed on glucose, but you've got 17 people that Food and Drug has received reports are dead, and 871 have been injured. You have laboratories, you tell us, that can't understand the instructions that they are getting. Now, maybe that's because you've got a group of obdurate manufacturers, but maybe it's because you've got blockheads in the laboratories, and I'm trying to understand which be the case.

Secretary SULLIVAN. Yes, Mr. Chairman. First of all, the reports of adverse reactions that I was referring to were to those tests that are for home use by the patients themselves and not——

Mr. DINGELL. Here, I'm talking about laboratories, and it should be of a higher level of competence.

Secretary SULLIVAN. Well,——

Mr. DINGELL. I'm not talking about home tests, what the guy pulls out of his bathroom shelf. I'm talking about the laboratory. Seventeen deaths, 871 injuries.

Secretary SULLIVAN. Let me have Dr. Mason comment.

Mr. MASON. We appreciate your bringing this up because we know you're concerned about waivered tests, and we've spent a lot of time on these as well.

Mr. DINGELL. But you waivered it.

Mr. MASON. Well,——

Mr. DINGELL. This test is waivered. You've got 17 people dead, and 871 injuries. Now, I assume that's not the entire universe of people who have been injured or died.

Mr. MASON. The——

Mr. DINGELL. But it is a test which is waivered, and I'm trying to understand how a test which would result in 17 deaths and 871 injuries out of 3,000 reports, is a test that should be waivered.

Mr. MASON. Let me try to explain that, and I'll go to the statute to start with. The statute specifies criteria for waived tests as those examinations and procedures that—one of the three criteria that—you can use them independently or together, and one of those has been cleared by the Food and Drug Administration for home use. So——

Mr. DINGELL. These are not home tests; these are laboratory tests.

Mr. MASON. Yes, they are. Yes, they are, sir. They are home tests.

Now, let me illustrate. I have a brother-in-law who is a diabetic and has had a stroke. My sister is a school teacher. She went down to a drugstore and bought the glucometer, opened it up, read the

directions, and she tests her husband three times a day, and she varies the insulin dose based upon the glucometer that she uses.

We're talking—the waived tests are these tests that have been approved by Food and Drug Administration for home use, and we felt that it doesn't make common sense, when my sister, who is a school teacher, or anyone in the Nation—literally hundreds of thousands of these have been sold, and they are being used in the home, and generally, when people follow the instructions—and as Secretary Sullivan has said, the instructions have not been particularly user-friendly, and we need to improve upon that, but we're talking about largely problems that have occurred in home use.

Now, there were three cases in a nursing home, and they were probably handled by nurses rather than lay people, but when FDA went in and looked at what had caused the problem, they were not using the glucometer according to the instructions associated with the kit.

Now, in waivered laboratories, for all eight of those waivered procedures, not only do they have to follow manufacturer's directions, but they have to use reasonable laboratory procedures.

We felt if we can allow these to be used in the homes of the Nation, that it did not make sense to say that a physician could not use one of these. In many areas where a physician would not apply for other types of laboratory, high complexity or moderate complexity, to deny that area of the physician even using a simple glucometer that can be used by my school teacher sister in the home just made no sense at all.

Mr. DINGELL. Well, the committee requested information from Food and Drug on these matters, and we were told that it had never been reviewed or requested before by anyone. Now, that means that if Food and Drug is correct on this, Food and Drug has never been inquired of on this matter. I'm trying to figure how that gives you a proper feed into your rulemaking and into your decisionmaking process, Doctor.

Mr. MASON. That really isn't true. We've worked——

Mr. DINGELL. Are you sure it isn't true? I'm curious, why would FDA be telling us that if it isn't true?

Mr. MASON. We have all of the data that you provided in terms of the adverse reactions and knew of those situations, the deaths, and we looked at the billions of tests that are performed and looked at the circumstances surrounding the misuse of the equipment, and we felt it would do a disservice to the community if we did not allow this to be a waiver test based upon information we had from FDA.

Mr. DINGELL. Well, it may very well be that I'm incorrect and you are correct. But let's look here. FDA told us that no information had ever been requested on any of the waivered tests.

Now, let's look at another example. There are numerous over-the-counter pregnancy testing kits widely used. FDA received 300 reports alleging 73 injuries. Now, does that indicate that there was proper information on how these particular test kits and devices were in fact working was considered by the Department?

Mr. MASON. Mr. Chairman, the history of how this proceeded is the first time that the Department went out for its regulations, there were 28 waivered tests, and with the comments—there were

4,600 comments that were directed specifically at waivered tests after the publications of the NPRM, and it was as a result of looking at those 4,600 comments, of talking again with people in the field and working closely with CDC and FDA that we decided that, after having gone through that process, we made a recommendation to the Secretary that those eight be left on the waivered test because they met the criteria in the statute.

Mr. DINGELL. Well, let's go to the next concern of the committee. Two of the waivered tests involve measuring hemoglobin levels. These tests, as you know, help detect anemia, which can be of very serious concern to the patients and to their doctors. These two tests are for hemoglobin, the non-automated copper sulfate method and the spun-micro-hematocrite.

These two tests were not waived in the proposed regulations. In fact, they were not included in the final draft regulations. Now, what would cause the administration and the Department to change that decision and to drop out those two?

Mr. MASON. Well, again, there were 28 on the original NPRM. Then there were 4,600 comments and further investigation, and I'm going to ask Dr. Roper to specifically address that.

Mr. ROPER. Sir, the hemoglobin done by the copper sulfate method and the spun-hematocrite are in the final regulation, and appropriately so. Those are very simple tests.

Mr. DINGELL. They are in the final regulation?

Mr. ROPER. Yes, sir.

Mr. DINGELL. And what do those final regulations provide? Are they waivered or not waivered?

Mr. ROPER. They are waivered tests in the final regulation.

Mr. DINGELL. Now, why are they waivered?

Mr. ROPER. Because they are very simple tests. The Secretary is a hematologist; I'm sure he can give you the best answer.

Secretary SULLIVAN. Yes. Mr. Chairman, these happen to be tests that any medical student or anyone who's ever attended a medical technology test can do. They are very simple. They are very broadly used. One would have to work hard to indeed get erroneous results from these.

So in other words, the level of simplicity for these tests is such and the utility, the broad utility of these tests is such that it is clearly appropriate that they be on the waived list. To have them done only by certified laboratories would be adding a level of inconvenience and cost that clearly would not be justified in view of the fact that these tests are so easily done and are so widely useful.

Mr. DINGELL. Well, let me raise a couple questions here. You received letters from two organizations, the American Society of Hematology and the American Society of Clinical Oncology, dated February 7, 1992—this all is less than a month before the final regs were published—and December 16, 1991, after the comment period on the regulations had closed.

Now, without objection, I will insert the two of these into the record.

[The letters follow:]

American Society of Hematology

1101 Connecticut Avenue, N.W. Seventh Floor
Washington, DC 20036-4303
Phone, 202/857-1118 • Facsimile, 202/223-4579

February 7, 1992

The Honorable Louis Sullivan
Secretary
Department of Human Resources
Room 615-F
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Lou:

On behalf of the members of the American Society of Hematology (ASH), I want to thank you for responding to my request for a meeting on the Clinical Laboratory Improvement Amendments of 1988 (CLIA'88) implementing regulations by arranging for members of your staff to meet with our representatives. Although I was unable to attend the meeting with Assistant Secretary Mason and his staff, I understand from H. Franklin Bunn, M.D. and other ASH representatives that the meeting was extremely productive. We appreciate the willingness of the Department to consider seriously the views of hematologists on these important regulations.

On behalf of the American Society of Hematology I would like to thank you for taking such an active interest in the development of these regulations. Implementation of CLIA'88 is a major step in the regulation of laboratory safety. Your continued personal interest and involvement will assure that it is a productive step for patients and physicians.

Again, thank you very much for responding to the request of the American Society of Hematology for a meeting on this important subject.

Sincerely,

George Stamatoyannopoulos, M.D.
President

AMERICAN SOCIETY OF CLINICAL ONCOLOGY ASCO

[illegible] North Michigan Ave. Suite 1717 Chicago, IL 60611-4067 312/644-0828 FAX: 312/644-8557 Executive Director James B. Ganzenberg
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Robert J. Mayer, M.D.

December 16, 1991

The Honorable Louis W. Sullivan, M.D.
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Room 615-F - HHH Bldg.
Washington, D.C. 20201

Dear Dr. Sullivan:

On behalf of the American Society of Clinical Oncology (ASCO), we are writing to request a personal meeting with you at the earliest possible date to discuss the impact of draft final regulations implementing the Clinical Laboratory Improvement Act of 1988 (CLIA '88). Our review of a current draft of the final regulations suggests that many hematologists and oncologists will be unable to perform in their offices blood tests for which they are completely qualified. The effect on patient care could be devastating.

We are particularly concerned that this issue has been resolved unsatisfactorily in the draft final regulations after a meeting with you in which we received assurances that the final regulations would not bar hematologists/oncologists from performing these routine tests in their offices. On August 8, 1990, Dr. Harvey M. Golomb, who was then President of ASCO, met with you and Dr. Mason to describe the problems for patients resulting from implementation of the proposed regulations. Dr. Golomb reported that you agreed that the proposed regulations should be changed to permit qualified hematologists and oncologists to continue these important office tests. For your convenience, we are enclosing copies of Dr. Golomb's correspondence with you and comments filed by ASCO.

We understand that the draft final regulations are still in circulation and have not yet been signed by you. We request that you turn your personal attention to this matter since others who have prepared the final draft perhaps do not comprehend how disruptive this regulation will be if adopted.

We will contact your office next week to schedule a meeting. We recognize that the American Society of Hematology has forwarded you a similar letter. We appreciate your intensive schedule, but this is an issue of critical importance to patients with cancer and hematologic diseases requiring the services of hematologists and oncologists.

Sincerely,

Martin Abeloff /sb

Martin D. Abeloff, M.D.
President

AMERICAN SOCIETY OF CLINICAL ONCOLOGY ASCO

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August 16, 1990

The Honorable Louis Sullivan
Secretary, Department of Health
and Human Services
200 Independence Avenue, NW
Washington, DC 20201

Dear Secretary Sullivan:

It was a great pleasure to meet with you and Assistant Secretary Dr. James Mason on Wednesday, August 8. I enjoyed our reminiscences about Boston City Hospital in the late 1960s and appreciated the opportunity to talk with both of you about the difficulties experienced by cancer patients because of Medicare carrier discretion in coverage decisions for off-labeled use of cancer drugs, treatment IND drugs, or phase I agents.

Also, I appreciated discussing with both of you how the proposed CLIA 1988 regulations would change the practice of hematology/oncology by placing the platelet count and differential in level 2, where supervision by a pathologist would be required. This approach could result in inordinate time delays for patients as well as a less trained individual interpreting laboratory tests important to chemotherapy planning and administration. We believe these tests should not be in level 2. As you suggested, we will forward a copy of our comments to Dr. Mason as soon as they are ready.

I am also pleased for ASCO to assist your efforts in improving the health of our population in any way I can. Certainly, the anti-smoking efforts that we jointly espouse stand out at the top of ASCO's list. Please feel free to contact me as the need arises.

Sincerely,

Harvey M. Golomb, M.D.
Professor of Medicine
Director,
Section of Hematology/Oncology
University of Chicago

HMG/ajt

Mr. DINGELL. Both express serious concern over the inclusion of tests routinely performed in hematologists' and oncologists' offices on the list of moderate test. The oncologists' letter requested a meeting with you, and the hematologist's letter thanked you, and I quote, "for arranging for members of your staff to meet with our representatives. Although I was unable to attend the meeting with Assistant Secretary Mason and his staff, I understand from H. Franklin Bunn, M.D., and other ASH representatives that the meeting was extremely productive."

Again, based on the hematologists' letter, apparently you arranged for Dr. Mason and others to meet with representatives of the society. Also, sometime in the next 2 weeks, the two tests were shifted to the waivered list.

Dr. Sullivan, I'm not going to say that these meetings were not ethical, and I'm not going to say that they were legal or illegal, but the correspondence and the meetings are curious in view of the fact that both Dr. Wilensky and Dr. Roper testified at a hearing last year that they specifically could not meet with anyone because the comment period was closed.

Is it appropriate that comments should be received after the comment period is closed? What is the Department's policy on meetings subsequent to the closing of the comment period?

Secretary SULLIVAN. Mr. Chairman, as I indicated in my formal statement, it is our policy, because of the great interest and importance of this issue, that we are continuing to receive information from the field because we recognize that this is an evolving situation. So it is in that spirit that the consultation with a number of groups has been ongoing. This is part of the public record of our meetings with various constituency groups designed to give us the best possible response.

Let me also comment on the letter from Dr. Bunn, whom I happen to know very well. He is president of the American Society of Hematology.

Dr. Bunn is an investigator at the Howard Hughes Institute at the Harvard Medical School. He is a research hematologist who does virtually zero clinical work, who would have absolutely no interest, financial or otherwise, in these tests.

His interest is that of a leader in the field of hematology with the desire to try and see that the best possible laboratory data is available for the care and diagnosis of our patients. So——

Mr. DINGELL. Let's look at this thing. The Administrative Procedures Act, which defines the way that regulations are issued—I'm sure you gentlemen are all familiar with it—requires that there be notice, hearing or opportunity for comment, and then essentially it requires that the comment period be closed. Then it allows you good gentlemen at the Department to proceed to make the decisions as to what it is you should do on the basis of the record which you have achieved.

Now, here we have a pair of tests which are of concern. You are going to write regulations. Regulations in their early draft form say that the two tests will not be on the list of waivered tests, but will fall into other categories.

After the comment period has closed, two groups come in and say we want to talk to you about these, and you then issue a regu-

lation which is different than that which had been in the original draft.

I'm not going to say this is an incorrect scientific conclusion. I'm not going to say it didn't meet the test that is imposed by the statute. But I am going to say that it doesn't appear to me to meet the requirements of complying with the Administrative Procedures Act.

Secretary SULLIVAN. Well, Mr. Chairman, I'm going to have Dr. Mason comment on this, but I want to again reiterate our objective is to get the best possible tests for our citizens in the least costly strategy, and that is our objective. It is not to have any underhanded dealings, any secret strategies. There's no——

Mr. DINGELL. I'm not——

Secretary SULLIVAN. There's no effort to——

Mr. DINGELL. I'm not alleging that. I'm just simply saying——

Secretary SULLIVAN [continuing]. Circumvent anything——

Mr. DINGELL [continuing]. That you didn't comply with the Administrative Procedures Act. One of my problems is that if you comply with the Administrative Procedures Act, everybody knows what the rules are. If you don't comply with it, some folks can come in and get special treatment.

Now, maybe what they are asking for is entirely proper, but under the Administrative Procedures Act, getting preferential treatment and getting treatment that's different than or better than what other people get is really not, I think, good or fair.

Secretary SULLIVAN. Mr. Chairman——

Mr. DINGELL. I'm not going into the question of illegality or anything else. I'm just saying, and my concern is, did you folks down there treat these groups differently and better by letting them be heard after the comment period was closed and after nobody else could come in and talk to you about these matters.

Secretary SULLIVAN. Mr. Chairman, the net result of our changes here would work against the financial interest of hematologists. The net result is that any physician, not simply a hematologist, would be able to do these tests in their laboratory.

So if anything, if indeed the implication is that there was some special interest to benefit the hematologists, the outcome here would be just the opposite of that. The objective here is to have the best available testing for our citizens at the least possible cost.

By having these waived tests, it means that any physician who has had the experience in his practice could actually have these tests performed in his or her laboratory, and this would in no—if anything, this opens it up rather than restricts it to the hematology community.

Mr. DINGELL. Here's the problem with that. I'm speaking like a lawyer and you're speaking like a doctor. The problem is that when we get into your turf, I'm pretty helpless; when you get into mine, you're probably not much better off than I was.

The Administrative Procedures Act says that there are certain things you do, and if you don't do them, you have not complied with the law. My problem is that here, you have apparently received comments after the time for the decisionmaking had commenced and after the time for closure of testimony and closure of receipt of comments had ended.

Now, Doctor, do you want to give me a comment here?

Mr. MASON. Thank you very much.

After the 60-some-odd-thousand comments came in on the NPRM, we felt within the Public Health Service that not only did we want to analyze those comments, but we needed consultation from experts in the field. As you well know, we talked to a lot of people—the three meetings in Atlanta where proficiency testing, cytology and other things were specifically discussed, where we met with experts in the field—and for my own self, I made myself available to any group that asked if they could come and visit with me. But I always consulted first with our general counsel, and I said, "Can I do that?" And I was told that we can if we were listeners, if a member of general counsel was there, and if notes were kept of what happened in the meeting.

I can say to you that we met with the oncologists, the hematologists and others, but I want you to know that that did—to my recollection, and I say that under oath, the waivered test did not even come up.

My concern in meeting with these groups, we were well along on our regulations and I wanted to make sure we hadn't overlooked something that was a fatal flaw.

We've put out some darn good regulations, but we wanted to make sure that there wasn't something in there that in some way wouldn't improve the quality of laboratory work in the Nation, and so we listened, and I think we've met the legal requirements of the administrative practice law. Although I'm not an attorney, that's the advice that we received.

Mr. DINGELL. Doctor, I think that it would be good for us both. If you were to check out what point in the rulemaking process you should stop talking to folks. I have a feeling——

Mr. MASON. We were listening.

Mr. DINGELL. I'm sure that you behaved in your view in an entirely honorable and proper fashion, but the hard fact of the matter is the law doesn't make much exception here for that particular condition.

The Chair is going to conclude at this time and recognize my good friend from Oregon.

Mr. WYDEN. Thank you, Mr. Chairman.

Dr. Sullivan, Dr. Mason, some moons ago, we were talking still about the matter of the good healthy HDL test, and I had one question that was raised by something you said to Chairman Dingell, Dr. Mason.

I understood you to say that there was not a standard at this point for what a good healthy HDL test ought to be to prevent coronary heart disease. If that is the case, Dr. Sullivan, do you think there ought to be a standard that would constitute what a good healthy HDL level ought to be given the fact that we're looking at the possibility of up to 100 million people having this test in the near future?

Secretary SULLIVAN. Again, Mr. Wyden, we believe that the HDL test is something that should be used not alone, standing alone, but in conjunction with the other clinical data of the patient. This is because this is a test that's not only complex, but also a test in

which the range of variation is such that it would be hazardous to make therapeutic decisions based upon use of that test alone.

Again, this is a field that is evolving. It doesn't mean that at some point, there would not be some level of accuracy or greater certainty in that particular test and we could change that. But at the present time, this is something that we believe is not appropriate to use standing alone in making therapeutic decisions.

Mr. WYDEN. Well, is the Agency for Health Care Policy and Research looking at this issue now so that we would be able to have some information on outcomes and be able to develop a standard?

I mean, it is one thing if we're talking about a test that would be used by a modest number of people and would not have wide-ranging implications. But you go through the data we have, newspaper headlines urging up to 100 million people, literally billions of dollars being spent.

I can accept the notion that you've articulated, Dr. Sullivan, that the field is evolving, but at what point—maybe this is appropriate for Dr. Mason—would we have some data, some outcomes data, say, from the Agency for Health Care Policy and Research or someone else, so that we could get a standard in place for a test that could involve up to 100 million people.

Dr. Mason.

Mr. MASON. I believe that CLIA 1988 will have a dramatic effect upon HDL in the United States of America because all the HDL determinations will be done in moderate and high complexity laboratories, and they will now fall under the provisions of proficiency testing.

So what will happen now, all laboratories in the Nation, at least that are in compliance with CLIA 1988, will be receiving three times a year five specimens where they will do an HDL determination and they will have to put—like shooting a bullet into a target—you don't have to hit the black every time, but you've got to get it in a certain range that will be relative to medical usefulness.

I think this will do a great deal to standardize the problem that we've been talking about, and if a laboratory can't get its results into that target area, then they won't be able to perform that test any longer, and I think that will have a significant effect upon standardizing the results of this particular test as well as some others that may have problems, too, with methodology.

Mr. WYDEN. Well, as we talked about earlier, there was some pretty wide discrepancy, Dr. Mason, between, you know, the targets. The target is 30 percent for HDL on one test, differential level in another area.

I would hope that the Department would move to set a standard for what constitutes a good healthy HDL level as it relates to the prevention of coronary heart disease given what I would expect to be enormous sums of money spent in this area, widespread use, and a very clear need for a sensible standard.

Dr. Sullivan, I wanted to finish up with some questions about the high risk test because I think all of us would agree that this is an area of concern. I'm specifically concerned about tests for AIDS and the PAP smears which were really the trigger for the inquiry

that Chairman Dingell focused on here in this subcommittee and I did in the Small Business Committee.

Now, with respect to AIDS test, at page 7,126 of the final regulation, the Department says, and I quote, "For example, accuracy in testing for AIDS is essential to limiting the spread of the disease. Both false positive and false negative results have serious personal and public consequences." Unquote.

The Department goes on to say, again I quote, "Current levels of performance are not minimizing public health risks as much as possible and recommends licensure and proficiency testing as a partial solution." Now, that is the conclusion of the Department, yet in spite of this conclusion of the Department, the Department also concluded, and I quote, "Laboratories should not be required to perform confirmatory testing for reactive HIV-I antibody tests."

Now, this would seem, at least when you read what the conclusion of the Department is and then the Department's conclusion about laboratories not being required to perform confirmatory tests, to be something of a contradiction.

What is your reaction to that, Dr. Sullivan?

Secretary SULLIVAN. Yes, Mr. Wyden. What is intended here is that for those screening laboratories that have positive test results, those would be referred to a reference laboratory for confirmation, you know, of those results.

This is because the complexity involved in this kind of test is such that, indeed, we'd want to be sure that the highest standards of quality in the performance of the tests are carried out.

Mr. WYDEN. Maybe Dr. Mason can get into this as well. Does it say that in the regulations, that there would have to be a referral to another set of laboratories, as Dr. Sullivan said, because that seems to me again to be a sensible public policy judgment. But all we have at this point is the Department says, look, you know, current levels of performance are not what we would like. The Department then says labs shouldn't be required to perform confirmatory testing. We don't see anything at this point about referrals to another set of labs for confirmatory tests.

Now, maybe I'm missing something, Dr. Mason, but if you could tell me where there is a requirement for a further referral, that would be helpful.

Mr. MASON. I think you are raising a very good point because it is very important that a positive test be confirmed. There's no question about that at all.

But I think we're trying to make CLIA 1988 do all things. There is a vast network of laboratories in the Nation where you have one step done at one lab and then a more highly procedurally difficult step done in another lab, and the referral pattern happens within the laboratory environment, but the requirement for the confirmatory test, that would come from another set of medical standards. In blood banks, you'd have a different standard.

In other words, all things are not required or mandated through CLIA 1988 that make the system work in the outside.

Mr. WYDEN. But is there a requirement for a confirmatory test? I mean, this seems to me to be a very, very substantial public health issue.

Mr. MASON. It's a standard of medical practice. In other words, a doctor wouldn't be willing to inform his patient or her patient that the person was HIV positive until there had been a confirmatory test. There is no law, and I don't think that CLIA was ever intended to mandate medical practice.

In other words, this tells who can do what test, but good medical practice would require that that confirmation be done.

Mr. WYDEN. I must tell you, I have to believe that it is in the public health interest to require a confirmatory test for a reactive HIV antibody test. Dr. Mason tells us that it's going to be done as a matter of medical practice, but, you know, possibly you have a situation of patients doing their own tests. It just seems to me that this ought to be a requirement. The Department feels otherwise?

Mr. MASON. Well, I can't speak for the Department; Dr. Sullivan can. But I'm just going to give you an opinion.

I don't agree with you that it needs to be required, but if it did need to be required, I wouldn't do it in CLIA 1988; I would do it in something that related to medical practice.

Mr. WYDEN. Well, that might be worth exploring. But, you know, it just seems to me that with the language that I have just gone through, we're sending the message that there's not a requirement as a matter of Federal policy for a confirmatory test for a reactive HIV antibody test, and if Dr. Mason believes it ought to be required somewhere else, that's something worth exploring as well. But we shouldn't be sending the message that I think you get out of the language that I read.

Dr. Roper.

Mr. ROPER. I just don't come to the conclusion you do, Congressman. What the language says is that a laboratory that does the basic HIV test is not required, themselves, to do the followup test. That is entirely separate from, is the practice of medicine these days to do a followup test whenever a positive is found? The answer to that question is absolutely yes.

If he sued, one of your friends would take that doctor to court if they did not proceed to do the followup test. It is just so simple and straightforward as that.

Mr. WYDEN. I'm not going to make a seat-of-the-pants judgment on the law here, but it seems to me if the Federal Government is saying laboratories should not be required to perform confirmatory tests, and we're hoping that medical practice will bear it out—and my notion of protection of patients consists of more than hoping that someone will go down to a Federal courthouse and prevail in Federal Court.

I don't think that litigation is the answer to everything and voted for our liability reform bill when we had it up here in this committee. I would hope that this would be a clear Federal requirement, that a confirmatory test be done, and I would be open to the suggestion that there are a number of ways to do it.

But I would think for the Federal Government to send the message that a lab should not be required to perform a confirmatory test would not be in the public health interest of the country.

Secretary SULLIVAN. Mr. Wyden, if I could comment, just to help this discussion. Let's take the case of cancer, another equally serious diagnosis. We don't have written in statute, the requirement

that if a doctor does a test that suggest that cancer is there, that there must be a confirmatory test, but in actual practice, this is almost always the case.

I happen to have, a few days ago, received a call from a personal friend where a diagnosis of possible ovarian cancer in his wife was made, and his immediate question is, I've been advised by the doctor who made this diagnosis that I should get a second opinion; whom would you recommend?

So, I think that's a good illustration of another area of an equally serious problem, even numerically, that affects our population even much moreso than the diagnosis of HIV. But as a standard medical practice for a serious illness of that nature that will determine one's projection of life expectancy, one's decisions on therapy and all of those other things that go into that, it is standard medical practice to be sure that one has an overwhelming body of evidence to confirm that diagnosis, because of the gravity of that.

So this would be the same with AIDS. With hear disease, if there's an EKG, the physician will look for confirmatory tests to see if there is heart disease, whether it's blood enzyme levels or echocardiograms or a whole series of x-ray tests or what have you. So, this is what we mean by standard medical practice.

I think if you were to try and write such a rule into law, the implications of this in terms of the regulatory burden for medical practice would be such that I think it would fall of its own weight, would be very expensive, and it really is already being done within the medical field.

Mr. WYDEN. I think what troubles me is that the Department, in the conclusion I read, made a formal statement that current levels of performance with respect to the AIDS tests were not minimizing public health risks in an adequate fashion. I mean, that was a finding of the Department, and then after that finding, the Department says labs don't have to do confirmatory tests.

I think that really does put this into a very different realm than the area of cancer where, it seems to me, you do make a plausible case that any time you have a serious health problem, if the tests aren't done adequately, then possibly someone is going to say it should be done.

But given the public health concern about AIDS in this country, your statement that current levels of performance don't minimize risk, and then we say no confirmation test is necessary, raises a concern.

It seems to me the chairman's gavel sends a relevant message that a member from Oregon ought to take notice of. Mr. Chairman, I thank you for the time. Dr. Sullivan, I thank you as well.

Mr. DINGELL. The Chair thanks the gentleman. The Chair will observe that we have to be careful also of Dr. Sullivan's time. Dr. Sullivan, on June 25, 1991, the subcommittee expressed its concerns over the process by which regulations were developed and the role of meetings at which no transcript was kept which were conducted in Atlanta last year.

The development of the complexity model and the categorization of thousands of lab tests on a 7-point rating scheme was an integral part of the regulations that was developed at those meetings, is that not so?

Secretary SULLIVAN. I'm sorry, could you repeat the question?

Mr. DINGELL. We sent you a letter on June 25, 1991. We expressed our concerns over a process by which regulations were developed. We discussed in that letter, meetings at which no transcripts were kept, that were conducted in Atlanta last year. The development of the complexity model and the categorization of thousands of lab tests on a seven-point rating scheme was an integral part of the regulations, isn't that correct?

Secretary SULLIVAN. Let me say this, Mr. Chairman; I'm not sure if I get the full part of your question. We, indeed, held a number of meetings with various individuals from the scientific community to get the best expertise that was possible.

This is part of an ongoing process that we always carry out in the Department. All of the results of those meetings with individual consultants have been made a part of our record. These were not secret meetings or anything of that nature, but we have both internal consultations in the Department and external consultations of individuals.

So we were seeking the best possible scientific advice on ways that we can implement the CLIA regulations.

Mr. DINGELL. Well, the concern of the question is two points: One, the complexity model and the categorization of thousands of lab tests was a part of the regulations. I think the answer to that question is yes.

The other was that we had sent you this letter in which we expressed concerns over regulations and the way they were developed, and we asked for the transcripts of the meetings. We were informed by the Department that there were no transcripts for those meetings.

Now, our concern is that the rulemaking process be regular, and that everybody be treated fairly. That's the purpose of the APA, the Administrative Procedures Act. Now, in addition to departmental officials, the meetings included a number of outside persons.

Now, the question is, how were the persons and the participants who were outside the Department, chosen for the three meetings in Atlanta? What qualifications did they meet?

Secretary SULLIVAN. Let me ask Dr. Roper to respond to that question, Mr. Chairman.

Mr. ROPER. One of the most helpful parts of this very good process was our invitation to a variety of consultants to come help us understand the problems posed by regulating laboratories. These were in three meetings, individual consultants who gave us a better understanding of the situation.

They were chosen because of their individual expertise in fields that we were interested in.

Mr. DINGELL. Now, you have submitted to us, a list, and after checking, it appears that the vast majority of these individuals have no lab experience, or that they haven't worked in the laboratories for years.

Don't we want people dealing with laboratory regulations to have had significant experience in that area?

Mr. ROPER. We want those people and we did include them, and we also want practitioners of medicine, since the most important part of CLIA is the extension of regulation to the private offices of

doctors. We want experts in the practice of laboratory medicine, a variety of individuals, just the sort that we included in our consultants.

Mr. DINGELL. Well, let's talk about this a little further. The College of American Pathologists, referred to ofttimes as CAP, is an organization that accredits and visits labs, probably more than any other organization, including the Department. That's a responsible organization, is it?

Mr. ROPER. Yes, sir.

Mr. DINGELL. And they have also accredited some 4,000 labs and are the largest supplier of proficiency testing materials in the country. They have expressed serious reservations about the key elements of the Department's regulatory framework.

Without objection, the Chair is going to put in the record a letter from CAP's President, Dr. David Senhauser.

[The letter follows:]

College of American Pathologists
325 Waukegan Road Northfield, Illinois 60093-2750
708/446-8800 FAX 708/446-8807

March 27, 1992

Public Health Service
Attention: CLIA *Federal Register* Notice
1600 Clifton Road, NE
Mail Stop MLR5
Atlanta, Georgia 30333

The College of American Pathologists (CAP) appreciates the opportunity to comment on the February 28, 1992, *Federal Register* announcement regarding the categorized list of CLIA laboratory test procedures. CAP is a medical specialty society of more than 12,000 board certified pathologists who provide pathology services to patients in hospitals, independent laboratories, clinics and other health care settings. The CAP currently inspects and accredits more than 4,000 laboratories and is the largest supplier of proficiency testing materials in the country.

CAP reviewed the criteria used by the Centers for Disease Control (CDC) to categorize the 10,000 test procedures. The use of the established seven criteria seems to be a logical approach to employ in categorizing clinical test procedures. However, we believe that in using the criteria, inaccurate scores were obtained for many of the moderate complexity test procedures and thus they should more appropriately be classified as high complexity. We plan to comment on the criteria and the scoring methods used to assign tests in our comments on the final CLIA rules.

Due to time constraints, we are unable to perform an extensive analysis of the list. We are planning to perform a detailed analysis of all CLIA test procedures at a later date. At this time we will submit to the CDC the scores obtained for each test procedure, verifying their reclassification from moderate complexity to high complexity. We strongly recommend that the list of CLIA test procedures be revised prior to implementation of the regulations on September 1, 1992.

Based upon our preliminary review, we provide for your consideration some of the test procedures currently classified as moderate complexity which should be reclassified as high complexity. Chairman of CAP's Scientific Resource Committees used the seven criteria as a basis for evaluating the attached list of procedures. The *Federal Register* states that test procedures receiving a score of above 12 were categorized as high complexity. Our experts concluded that the test procedures on the attached list should always receive a score higher than 12 under the scoring system used by CDC.

Thank you for considering our recommendations. If you should have any questions on this issue please contact Deidra Abbott of CAP's Division of Government and Professional Affairs at (202) 371-6617.

Sincerely,

Donald A. Senhauser, MD
President

College of American Pathologists

RECLASSIFICATION OF CLIA TEST PROCEDURES FROM MODERATE COMPLEXITY TO HIGH COMPLEXITY

It is the consensus of Chairman of our Scientific Resource Committees that the following test procedures, listed according to their specialty, should be reclassified from moderate complexity to high complexity. Each of the following procedures was graded to determine the level of complexity by using the seven criteria: 1) knowledge; 2) training and experience; 3) reagents and materials preparation: 4) characteristics of operational steps; 5) characteristics and availability of calibration, quality control and proficiency testing materials; 6) test system troubleshooting and equipment maintenance; and 7) interpretation and judgement. Based upon these criteria, each procedure receives a score greater than 12 due to the high level of complexity required to accurately interpret the results of each procedure. Moreover, an inaccurate interpretation of these tests could contribute to inaccurate diagnosis of a patient's condition and therefore significantly affect patient care outcomes.[1]

Chemistry

Test Analyte 1: **Blood Gases**

Discussion: Blood gas testing should be reclassified to high complexity even when performed on an automated analyzer. Special training and knowledge is required for proper sample evaluation over and above that required for patient samples. Decision-making and direct intervention is required to perform most troubleshooting and problem solving operations. Also, judgement is needed for optimal pre and post analytical steps.

Subspecialty: Urinalysis

Test Analyte 1: **Urinary Sediment Microscopic Elements**

Discussion: Urinary Sediment, as with all forms of microscopy, should be reclassified as high complexity due to the expertise and experience required to obtain an accurate diagnosis and the severe consequences which may occur from an inaccurate diagnosis. For example, the incompetent microscopist may fail to recognize RBC casts and allows a treatable glomerulonephritis to progress.

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[1]Time constraints precluded analysis of all procedures listed. We confined our review to a limited number of test procedures that could be quickly identified as possibly miscategorized.

Another example is that yeast forms may be confused with RBC and antifungal therapy is not given.

Hematology

Test Analyte 1: **All Combined Blood Counts (CBCs) with differential** (WBC count, Hematocrit, Hemoglobin, Platelet count, RBC count, WBC differential)

Discussion: All CBCs and their individual components, whether performed manually, or on automated/semi-automated instruments, should be reclassified as high complexity due to the required high levels of knowledge, training, experience, interpretation and judgement of individuals performing the test. Operator intervention is also required. For example, failure of the operator to recognize nucleated erythrocytes on the RBC histogram/cystogram leads to a spuriously reported high WBC count. As a result, a patient with abdominal pain may be taken erroneously to the operating room for surgery of nonexistent acute appendicitis or the patient may be inappropriately treated with antibiotics for a presumed infection.

Microbiology

Subspecialty: Bacteriology

Test Analyte 1: **Campylobacter**

Test Analyte 2: **Hemophilus Influenzae Types A through F**

Test Analyte 3: **Helicobacter Pylori**

Test Analyte 4: **Legionella Pneumophila**

Test Analyte 5: **Neisseria (all meningitides types)**

Test Analyte 6: **Salmonella**

Test Category 1: **Gram Stain**

Discussion: Campylobacter, Haemophilus influenzae types A through F, Helicobacter pylori, Legionella pneumophila, Neisseria, and Salmonella are all

organisms normally associated with procedures classified in the high complexity category. In addition, these tests require additional experience and/or serological procedures to make accurate interpretations. The serological grouping and typing is specifically identified as being part of the high complexity test list.

Although the testing procedure required for Gram stain is fairly simple, the interpretation, judgement knowledge and experience required to obtain an accurate result is complex. Even skilled personnel may have difficulty making accurate interpretations.

Subspecialty: Mycology

Test Analyte 1: **Cryptococcus**

Test Analyte 2: **All Fungi**

Test Analyte 3: **Yeast**

Discussion: Cryptococcus requires extensive training and knowledge above the level of most test categories of moderate complexity. Test procedures such as these requiring interpretations of cultures or isolation of organisms involve significant judgement and advanced technical skills.

Subspecialty: Parasitology

Test Analyte 1: **Intestinal Parasites**

Discussion: This analyte requires extensive knowledge, training, experience, interpretation and judgement. In addition, the calibration required for this test procedure is very complex.

Subspecialty: Virology

Test Analyte 1: **Adenovirus**

Test Analyte 2: **Herpes Simplex**

Test Analyte 3: **Respiratory Syncytial Virus**

Test Analyte 4: **Respiratory Viruses (influenza A and B, parainfluenza)**

Test Analyte 5: **Rotavirus**

Discussion: Sophisticated judgement and advanced technology is required by testing personnel to accurately interpret cultures.

Mr. DINGELL. In that letter, CAP stated, and I quote, "CAP reviewed the criteria used by the Centers for Disease Control to categorize the 10,000 test procedures. The use of the established seven criteria seems to be a logical approach to employ in categorizing clinical test procedures. However, we believe that in using the criteria, inaccurate scores were obtained for many of the moderate-complexity test procedures. Thus, they should more appropriately be classified as high complexity. We strongly recommend that the list of the CLIA test procedures be revised prior to implementation of the regulations on September 1, 1992."

Now, that letter was sent to the Public Health Service, attention CLIA Register Notice.

Mr. ROPER. Yes, sir, and we plan to do that.

Mr. DINGELL. Now,—I beg your pardon?

Mr. ROPER. We plan to do that. We are receiving comments from individuals who believe that tests have been mis——

Mr. DINGELL. Well, the letter——

Mr. ROPER. May I finish my answer?

Mr. DINGELL. The letter is dated March 27.

Mr. ROPER. Yes, sir. We intended to do that even before we got their letter. Individuals who think that tests have been improperly classified are making that known to us, and we plan to publish a final list of the classifications in September.

Mr. DINGELL. Mr. Secretary, I gather that CAP wasn't the only private sector group with so-called "deemed-status" under the old CLIA regs to whom the Department delegated the bulk of its survey and approval process, is that correct?

Mr. MASON. That was not the only one. That is correct.

Mr. DINGELL. It wasn't the only one, OK.

What, if anything, will the Department do based on CAP's warning about your complexity model?

You have indicated you intend to review those matters. Will this cause you to contemplate reclassifying tests, and reviewing the tests?

Secretary SULLIVAN. Yes, Mr. Chairman. We, indeed, evaluate all of the comments we receive, and we certainly have made changes already in our proposals based upon those comments.

I think we would need to, as in the case with any comments, assess all of them, and to make a determination about the validity or the merit of those recommendations. So, clearly, we would be looking at these comments and others that would be coming in.

Mr. DINGELL. Doctor, the statute had some specific statements in it, and I am going to quote from the statute. It said, "Qualifications shall, as appropriate, be different on the basis of the type of examinations and procedures being performed by the laboratory, and the risks and consequences of erroneous results associated with such examinations and procedures."

Dr. Sullivan, the seven criteria used to develop the complexity model do not include any assessment of risk. I am curious, should risk assessment be included in that, and can you tell us what is the reason for the exclusion of risks associated with inaccurate test results despite what I regard as rather specific direction by the Congress?

Secretary SULLIVAN. Let me have Dr. Mason respond to that, Mr. Chairman.

Mr. MASON. Mr. Chairman, we feel that there is some element of risk in all of the determinations in the moderate and high complexity model, and it is separating that out.

Mr. DINGELL. Doctor, I don't quarrel with that.

Mr. MASON. But when you look at the seven criteria, they relate to knowledge needed, training and experience, reagent and proper materials preparation, characteristics of the operational steps, characteristics and availability of calibration, quality control and proficiency testing, troubleshooting and maintenance required, and a degree of interpretation and judgment, and all of those are part of a risk assessment.

Risk was the underlying factor in all of these, and these were ways to quantify risk.

Mr. DINGELL. Do you feel that you have adequately quantified risk in connection with those tests?

Mr. MASON. I think we have made a best-attempt effort to do that. I am comfortable. We are going to look at other comments, but we have done our best to put those where they ought to be in terms of moderate and high complexity.

Mr. DINGELL. I am trying rather carefully not to influence your rulemaking process, but, by the same token, I want to be sure that it is progressing in a proper fashion, and a proper direction.

Is it a bad idea to just include risk in there?

Mr. MASON. All of those factors.

Mr. DINGELL. Dr. Roper, I will be glad to hear your comments, too.

Mr. ROPER. Excuse me, Dr. Mason.

I was just going to say, risk is implicit in each of those factors, the same point Dr. Mason made earlier.

Mr. DINGELL. Of course, risk assessment is a term of art. We are not getting risk assessment on all kinds of things. It is a term of art, is it not?

Mr. MASON. Yes, it is very much. Everything we do is balancing risk with benefits, and I think that kind of a risk assessment has gone into the categorization model.

We are not saying it is perfect, but we are saying it is darned good, and as time goes on that is another reason why Secretary Sullivan has called for an advisory committee. They will play a substantial and major role in the future at looking at what is in moderate complexity and what is high complexity.

As new instrumentation is developed, one of the things that we really want to build into this is doing nothing that would reduce innovation, and that is why FDA is going to combine 510(k) review with CLIA 1988, so that manufacturers—there are going to be a lot of manufacturers out there who will try to devise instruments that will take a test that today is high complexity, and with better instrumentation and built-in quality control, over time, these may move down into moderate complexity—so it is dynamic—or we may find, as we look at proficiency testing results, that maybe one has been misclassified and needs to go the other way.

But I think this is a dynamic process, it is a judgmental one, and CDC, I think, has done an absolutely commendable job of trying to

relate risk to what happens out there, and get the best possible input from varied sectors to help in that process.

Mr. DINGELL. Thank you, Doctor.

Gentlemen, the Chair notes that we promised, Dr. Sullivan, that we would have you out of here by 5 o'clock. We have come pretty close. You should, indeed, be surprised that we have come close. It is a rare, rare event.

Having said that, we will have some additional questions for the Department which I would like to submit to you in writing and, without objection, we will keep the record open.

These are going to include, amongst other things, labelling requirements by FDA, additional delays in requiring certain actions, quality assurance, quality control, and personnel. Some things which we find to be serious gaps in the enforcement, inspection and regulations, and significant problems with inaccurate and potentially dangerous mammography to detect breast cancer.

As you know, this is a very major problem in this country. Recognizing that mammography is probably an interpretation, and mammographs are probably less science than art, but it is a very major problem. So we will submit those to you in writing, Doctor, and if you and Dr. Mason can give us an answer, we will be very appreciative.

Gentlemen, we are 9 minutes late releasing you.

Dr. Sullivan, Dr. Mason, Dr. Roper, Mr. Toby, in any case, we thank you for your assistance to the committee.

Secretary SULLIVAN. Thank you.

Mr. DINGELL. The subcommittee is adjourned until the call of the Chair.

[Whereupon, at 5:09 p.m., the hearing adjourned.]

[The following material was submitted for the record:]

AMERICAN ACADEMY OF NEUROLOGY

IMPLEMENTATION OF CLIA '88

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

HEARING STATEMENT

APRIL 29, 1992

The American Academy of Neurology (the Academy) welcomes this opportunity to provide comments on the February 28, 1992 final rule implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). AAN is the largest national organization of neurologists and neuroscientists, with over 11,000 members devoted to research, care and treatment of people with neurological disorders.

Personnel Requirements for the Technical Supervisor of a High Complexity Laboratory Performing Muscle and Nerve Tissue Biopsies

The Academy is very concerned with the provision in the final rule which permits only board certified pathologists (or under their direction, residents who have responsibility for the exam and interpretation of histopathology specimens) to meet the requirements of the Technical Supervisor position in a High Complexity laboratory performing tests in the subspecialty of histopathology. Since muscle and nerve tissue biopsies fall under histopathology, this provision excludes neurologists from performing the tests that they have historically pioneered and who are internationally recognized for their expertise in this area. Neurologists who are specially trained and experienced in the area of neuromuscular disease pathology, including the processing and interpretation of muscle and nerve biopsies, are the best qualified candidates to fill this role. In fact, the majority of muscle and nerve biopsy specimens in this country are being evaluated in specialized laboratories headed by board certified neurologists, not pathologists. While there are some pathologists who have gained expertise in this specialized discipline, most often through training programs headed by a neurologist expert in the field, their numbers remain insufficient to meet the demand.

If the final regulations are implemented as written, the quality and control of muscle and nerve biopsy specimen handling and interpretation will significantly diminish. The majority of muscle and nerve biopsies will wind up in the hands of non-experts and existing recognized facilities in this field will be dismantled.

For the above reasons, the Academy strongly urges HCFA to grant specially trained and experienced neurologists a status which will enable them to fulfill the Technical Supervisor requirement for High Complexity labs which conduct tests in the subspecialty of histopathology or specifically in the area of muscle and nerve tissue biopsies. The Academy recommends that HCFA establish the personnel requirements as follows: that the Technical Supervisor for labs which perform tests in the subspecialty of muscle and nerve histopathology be a Board Certified Neurologist, who has successfully completed at least one year of a fellowship training program in neuromuscular pathology with direct laboratory experience in the preparation and interpretation of muscle and nerve biopsies, and who has a minimum of one year of experience conducting such tests; or be a Board Certified Pathologist with equal training and experience in this area.

If the final rule on CLIA is not revised per the above recommendation, HCFA will create a scenario in which the quality of clinical laboratory testing in the area of neuromuscular pathology will be adversely impacted. If the intent of CLIA is to improve quality, then the Academy hopes HCFA will incorporate its recommendation into the regulations.

Thank you for this opportunity to present our views. We look forward to working with you on this issue.

American Association of Clinical Endocrinologists

STATEMENT FOR THE RECORD

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

COMMITTEE ON ENERGY AND COMMERCE

IMPLEMENTATION OF CLIA '88

APRIL 29, 1992

The American Association of Clinical Endocrinologists (AACE) welcomes this opportunity to comment on the February 28, 1992 final rule implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88).

AACE is a new national organization. We were founded in the spring of 1991 to create a unified voice for clinical endocrinologists, nationwide, on issues affecting health care and the practice of endocrinology. AACE has approximately 1500 members representing 50 states. Our activities are currently directed by a twenty-eight member Steering Committee representing 15 states. AACE is deeply committed to serving as an advocate on behalf of both patients and physicians on issues affecting the accessibility, cost, and quality of health care.

Overall Impression of Final Rule

AACE commends the Health Care Financing Administration (HCFA) and the Centers for Disease Control (CDC) for crafting such a well-balanced regulation although some issues remain to be addressed and the regulation refined further. The final rule is a big improvement over the proposed rule in terms of access to laboratory testing, personnel requirements, and the regulatory scheme, known as the "complexity model," created to classify the level of regulation needed for every clinical lab. AACE especially applauds HCFA and CDC for creating this complexity model which classifies the level of regulation for laboratories based on the complexity of the methods employed, e.g., automated, semi-automated, and manual, as opposed to the proposed rule which classified labs merely by analyte. We remain concerned about the time-frame for phase-in of implementation of the regulation given the obvious necessity to educate the medical profession on compliance. Enormous educational efforts will be required to ensure a smooth and fair implementation of the CLIA requirements; and it will take considerable cooperation between the medical profession, HCFA, and state agencies. In this regard, AACE is available to work with all concerned parties.

Continuing Medical Education (CME)

AACE is concerned with the feasibility and practicality of developing unified standards for continuing medical education (CME) programs for those physicians that want to serve as Director and Technical Consultant for their own Moderate Complexity lab or Director and Technical Supervisor for their own High Complexity lab, but who do not have the requisite training or

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experience. As you know, the final rule allows for physicians to acquire 20 hours of CME to fill the role of Director for a Moderate Complexity lab. We support this provision which provides an option to those physicians who do not have the one year of lab training during residency or who do not have the one year of experience supervising a Moderate Complexity lab, but are concerned that 20 hours may be unnecessary. This option will likely be used by new physicians.

The final regulation, however, does not provide physicians with a CME option to fulfill the requirements for the Technical Consultant position for a Moderate Complexity lab, nor does it provide physicians with the CME option to meet the personnel requirements for Director and Technical Supervisor for a High Complexity lab. AACE urges HCFA to provide physicians who do not have the requisite training or experience with the opportunity to meet these requirements through CME course work. AACE believes that it is possible to develop curriculums for two CME courses: one which covers both the responsibilities of Director and Technical Consultant for a Moderate Complexity lab; and one which covers the responsibilities for Director and Technical Supervisor for a High Complexity lab. Further discussion would be needed to determine the appropriate amount of hours and the curriculum for each course.

Given the task of developing such CME courses, AACE asks that HCFA move up the effective date for CME requirements to September 1, 1994 at the earliest so that the medical profession will have enough time to develop the necessary curriculum. The final rule offers two effective dates: in the preamble the date given is February 28, 1993 while the regulatory language states August 2, 1993.

Unannounced Inspections

AACE remains concerned with the Department's plans to conduct unannounced inspections in physicians' office labs (POLs) and the costs of those inspections. First, because physicians in POL settings also provide direct patient care, we believe that unannounced inspections will cause undue disruption to patients who are scheduled to be seen on that day and thereafter. Physicians who serve in the capacity of Director and fill other personnel requirements for their lab would need to spend time with the inspector during the visit thereby requiring the rescheduling of patient visits and disrupting care. For this reason alone, HCFA should allow at least five working days advance notice for inspections in POLs. We do not believe that physicians will wait to the last minute to comply with CLIA and scramble for compliance during the advance notice period. Second, because POLs commonly utilize only part-time lab personnel, especially if the volume of testing is low, an inspector may show up when the lab is not in operation. This will cause increased costs to the program in that the inspector will have to return to the site at a future time to inspect the lab. These unnecessary costs to the program would also be incurred if the physician's office was closed entirely upon the inspector's arrival. We realize that compliance fees are dealt with under another final regulation, and are not subject to comment on this issue, but we remain concerned that the costs of inspections not be excessive or financially prohibitive for POLs. For these reasons, we urge HCFA to allow only for announced inspections with advance notice for POLs so that patient care is not disrupted, patient visits do not have to be rescheduled, and so the program is more efficient, reducing costs.

Documentation of Experience

The final rule is unclear as to how physicians will demonstrate that they have the required "experience" necessary to fill the roles of Director and Technical Consultant for Moderate Complexity labs, and Director and Technical Supervisor for High Complexity laboratories. We understand that inspectors will need flexible instructions to help them determine whether a physician has the requisite experience to serve in these capacities, and that HCFA has asked the medical profession for guidance in this area. AACE believes that the best way for physicians to demonstrate to HCFA that they have the requisite experience is to sign a statement attesting the fact that they have such experience, or for physicians new to laboratory work, to have taken the necessary CME courses. In the latter case, a certificate indicating that the CME course work was successfully completed should serve as sufficient proof to the inspector. Should HCFA suspect that the physician has made a false statement, additional documentation which shows, for example, successful participation in a proficiency testing program, Medicare billing for lab tests, completion of training programs, a bill of sale for the lab equipment, or other such additional documentation could be provided.

Endocrinology Training and Experience

We understand the HCFA is currently looking at residency and fellowship programs and Board certification requirements for different specialties to determine whether or not they include appropriate training in clinical laboratory testing. We note that HCFA specifically mentions, as an example, physicians certified in either hematology or hematology and medical oncology by the American Board of Internal Medicine as meeting the "training" (as part of the "training or experience") personnel requirements to direct a Moderate or High Complexity lab, since these boards require the physician to have completed one year of lab training during (sic) residency (fellowship). Endocrinology fellowship programs include at least one year of specialized lab training in clinical chemistry, radioimmunoassay, and radioisotope lab services among others. A three year residency program in internal medicine and a two year fellowship program (with one year of lab training) are required by the American Board of Internal Medicine for certification in endocrinology just as in the case for hematology and hematology/oncology. The lab training required for endocrinologists is no less stringent than that required for either hematologists or the hematologist/oncologist. For these reasons, AACE strongly urges that HCFA specifically list board certified or eligible endocrinologists (or simply those who have successfully completed a two year endocrinology fellowship program) as those who meet the training requirements necessary to fulfill the director function in either a Moderate or High Complexity lab. Additionally, by citing endocrinology board certification or eligibility or fellowship training, HCFA inspectors will be able to more easily and readily identify those who meet the training requirements. AACE would be pleased to provide HCFA staff with a synopsis of the rigorous residency and fellowship training programs that endocrinologists go through and the subsequent board certification requirements for endocrinology.

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IMPLEMENTATION OF THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988

STATEMENT FOR THE HEARING

ENERGY AND COMMERCE SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATION

APRIL 29, 1992

The American College of Rheumatology (the College) appreciates this opportunity to comment on the February 28, 1992 final rule implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88).

These comments will, first, briefly provide background on the mission of the College and the role of rheumatologists in the health care system to highlight the unique nature of our medical specialty. Then, our comments will specifically focus on the final rule.

The American College of Rheumatology is the professional organization of rheumatologists. It includes practicing physicians and research scientists who are dedicated to preventing disability, healing and eventually curing more than 100 types of arthritis and related disabling and sometimes fatal disorders of the joints, muscles, and bones.

A rheumatologist is a physician specialist who provides medical care to patients with rheumatic diseases which affect not only bones, joints and muscles, but also the immune system, heart, lungs, gastrointestinal tract and kidneys. Osteoarthritis, rheumatoid arthritis, gout, systemic lupus erythematosus, bursitis, and osteoporosis are only representative of the more than one hundred different kinds of rheumatic diseases cared for by a rheumatologist. These diseases affect more than 37 million people in the United States, and are the leading cause of disability and absenteeism in the work place. With special training and expertise, rheumatologists are uniquely qualified among physician specialists to provide high quality medical care, including the necessary clinical laboratory testing for diagnosis and treatment purposes, to people with rheumatic disease in a cost-effective manner, and to lead the team of health care professionals who assist in treating and caring for people with these disorders.

Overall Impression of Final Rule

The College thanks the Health Care Financing Administration (HCFA) and the Centers for Disease Control (CDC) for developing such a well-balanced regulation although some issues remain to be addressed and the regulation refined further. The final rule is a big improvement over the proposed rule in terms of access to laboratory testing, personnel requirements, and the regulatory scheme, known as the "complexity model," created to classify the level of regulation needed for every clinical lab. The College especially endorses this complexity model which classifies the level of regulation for laboratories based on the complexity of the methods employed, e.g.,

automated, semi-automated, and manual, as opposed to the proposed rule which classified labs merely by analyte. We remain concerned about the time-frame for phase-in of implementation of the regulation given the obvious necessity to educate the medical profession on compliance. Enormous educational efforts will be required to ensure a smooth and fair implementation of the CLIA requirements; and it will take considerable cooperation between the medical profession, HCFA, and state agencies. In this regard, the College is available to work with all concerned parties.

Documentation of Experience

The final rule is unclear as to how physicians will demonstrate that they have the required "experience" necessary to fill the roles of Director and Technical Consultant for Moderately Complex labs, and Director and Technical Supervisor for High Complexity laboratories. We understand that inspectors will need flexible instructions to help them determine whether a physician has the requisite experience to serve in these capacities, and that HCFA has asked the medical profession for guidance in this area. The College believes that the best way for physicians to demonstrate to HCFA that they have the requisite experience is to sign a statement attesting and documenting the fact that they have such experience, or for physicians new to laboratory work, to have taken the necessary CME courses. In the latter case, a certificate indicating that the CME course work was successfully completed should serve as sufficient proof to the inspector. Should HCFA suspect that the physician has made a false statement, additional documentation which shows, for example, successful participation in a proficiency testing program, Medicare billing for lab tests, completion of training programs, a bill of sale for the lab equipment, or other such additional documentation could be provided.

Continuing Medical Education (CME)

The College is concerned with the feasibility and practicality of developing unified standards for continuing medical education (CME) programs for those physicians that want to serve as Director and Technical Consultant for their own Moderate Complexity lab or Director and Technical Supervisor for their own High Complexity lab, but who do not have the requisite training or experience. As you know, the final rule allows for physicians to acquire 20 hours of CME to fill the role of Director for a Moderately Complex lab. We support this provision which provides an option to those physicians who do not have the one year of lab training during residency or who do not have the one year of experience supervising a Moderately Complex lab, but are concerned that 20 hours may be inappropriate. This option will likely be used by new physicians.

The final regulation, however, does not provide physicians with a CME option to fulfill the requirements for the Technical Consultant position for a Moderately Complex lab, nor does it provide physicians with the CME option to meet the personnel requirements for Director and Technical Supervisor for a Highly Complex lab. The College urges HCFA to provide physicians who do not have the requisite training or experience with the opportunity to meet these requirements through CME course work. The College believes that it is possible to develop curriculums for two CME courses: one which covers both the responsibilities of Director and Technical Consultant for a Moderately Complex lab; and one which covers the responsibilities for Director and Technical Supervisor for a Highly Complex lab. Further discussion would be needed to determine the appropriate amount of hours for each course.

Given the task of developing such CME courses, the College asks that HCFA move up the effective date for CME requirements to September 1, 1994 at the earliest so that the medical profession will have enough time to develop the necessary curriculum. The final rule offers two effective dates: in the preamble the date given is February 28, 1993 while the regulatory language states August 2, 1993.

Unannounced Inspections

The College remains concerned with the Department's plans to conduct unannounced inspections in physicians' office labs (POLs) and the costs of those inspections. First, because physicians in POL settings also provide direct patient care, we believe that unannounced inspections will cause undue disruption to patients who are scheduled to be seen on that day and thereafter. Physicians who serve in the capacity of Director and fill other personnel requirements for their lab would need to spend time with the inspector during the visit thereby requiring the rescheduling of patient visits and disrupting care. For this reason alone, HCFA should allow at least one week advanced notice for inspections in POLs. We do not believe that physicians will wait to the last minute to comply with CLIA and scramble for compliance during the one (or more) week notice period. Second, because POLs commonly utilize only part-time lab personnel, especially if the volume of testing is low, an inspector may show up when the lab is not in operation. This will cause increased costs to the program in that the inspector will have to return to the site at a future time to inspect the lab. These unnecessary costs to the program would also be incurred if the physician's office was closed entirely upon the inspector's arrival. We realize that compliance fees are dealt with under another final regulation, and are not subject to comment on this issue, but we remain concerned that the costs of inspections not be excessive or financially prohibitive for POLs. For these reasons, we urge HCFA to allow only for announced inspections with at least one week notice for POLs so that patient care is not disrupted and patient visits do not have to be rescheduled, and so that the costs to the program are more efficient.

Rheumatologists Office Labs: Testing and Personnel Requirements

Synovial Fluid Analysis -- The final rule places "crystal analyses of joint fluid" under the moderate complexity category of regulation, while white cell analysis of joint fluid is not listed anywhere. We believe this to be an oversight and recommend that HCFA place both crystal and white cell analysis of joint fluid using an automated technique in the moderate complexity category, or HCFA could simply add "synovial fluid analysis" to the moderate complexity category as it is these two elements that compose a "synovial fluid analysis."

Board Certification in Rheumatology -- We understand the HCFA is currently looking at residency programs and Board certification requirements for different specialties to determine whether or not they include appropriate training in clinical laboratory testing. We note that HCFA specifically mentions, as an example, physicians certified in either hematology or medical oncology by the American Board of Internal Medicine (ABIM) as meeting the "training" (as part of the "training or experience") personnel requirements to direct a Moderate or High Complexity lab. Rheumatology residency programs require that the physician acquire clinical competence in the scientific basis of the methodology, indications, and interpretation of laboratory tests used in diagnosis and follow-up of patients with rheumatic diseases. The curriculum for rheumatology residency programs (and ABIM Board eligibility) is therefore no less stringent in the area of clinical lab testing than that for hematology or medical oncology. For ease in identifying appropriately trained physicians, the College asks that HCFA specifically name board certified or eligible rheumatologists as those who meet the training requirements necessary to fulfill the director function in either a Moderate or High Complexity lab. The College would be pleased to provide HCFA staff with a synopsis of the residency training programs that rheumatologists go through and the subsequent board certification requirements for rheumatology.

american society of internal medicine

April 29, 1992

Rep. John Dingell, Chairman
Subcommittee on Oversight and Investigations
2323 Rayburn House Office Building
Washington, D.C. 20515

Dear Rep. Dingell:

The American Society of Internal Medicine (ASIM) requests that you include this statement as a part of the written record for the April 29 hearing of the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce on the implementation of CLIA 88. As you know, the Society strongly supported the CLIA 88 legislation and has continued to advocate the development of practical and cost-effective regulations that preserve access to physician office laboratory (POL) testing. ASIM believes that the Department of Health and Human Services (HHS) did a remarkable job developing regulations that recognize the complexity of testing being performed in a laboratory, preserve access to physician office laboratory testing and ensure quality and accuracy of testing.

ASIM would like to call your attention to the Society's position of strong support of the final personnel standards and the categorization of tests. Recall that under the *proposed rule* two stipulations would have created an undesired effect of closing most physician office laboratories (POL). First, a majority of the tests--even those analytes performed with methods especially designed for the POL setting that are very accurate and easy to use--would have been stringently regulated in the Level II category of testing (now called high complexity testing). Second, HHS relied almost exclusively on the educational training and expertise of laboratory personnel as the only way to ensure quality laboratory testing. For example, under the proposed rule, most physicians with laboratories would have been required to hire a pathologist and medical technologist to direct a laboratory and perform testing. Placing a heavy reliance on the educational training of personnel would have been very costly and unnecessary, particularly for POLs. Many of the automated and semi-automated instruments, simple kits and assays designed for the physician office laboratory setting are easy to use, are very accurate and do not require laboratory personnel with years of educational training to operate. This approach would have been unworkable, as well, given the shortage of laboratory personnel in many communities.

ASIM argued in comments submitted August 20, 1990 to HHS that those instruments, kits and assays commonly performed in a POL--given their simplicity and accuracy--should be categorized as moderate complexity testing. Additionally, a three-pronged approach, which emphasizes a laboratory's participation in proficiency testing (PT) ***and*** the performance of quality control (QC) and quality assurance (QA) activities, in addition to workable personnel requirements, is the most cost-effective and practical approach to the regulation of laboratory testing. The final regulations accomplish both of these objectives. Most analytes, specifically in the specialties of

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chemistry, hematology, bacteriology, virology and immunology, that are performed in a POL using state-of-the-art automated and semi-automated instruments, simple kits and assays that allow tests to be performed more accurately and quickly with little chance of inaccurate results are now categorized as moderate complexity testing. Given the shift of tests from high to moderate complexity, HCFA strengthened the moderate complexity personnel standards (formerly Level 1). Under the proposed rule no training or experience was required for a physician to serve as the director of a Level I laboratory (now called moderate complexity testing). Under the final rule, physicians will either need to have laboratory training during medical residency, one year experience directing or supervising non-waived testing or 20 hours of continuing medical education (CME) in laboratory testing to direct a laboratory performing moderate complexity testing. Additionally, HHS created a new position of *technical consultant* to assist physicians who do not meet the one year training or experience qualifications of a technical consultant to hire a qualified individual to assist in the establishment of QC and QA program and to ensure the laboratory's participation in PT. The technical consultant would only have to be accessible to the director and laboratory personnel on an as needed basis. The personnel standards for high complexity testing are appropriately more stringent than the standards for moderate complexity testing. Unlike the proposed rule, which was rigid in its approach to the Level II personnel standards (now called high complexity testing)--strictly requiring a pathologist director and other highly trained laboratory personnel--the final rule is flexible in that *several* appropriately degreed persons with proper training or experience could fill the various managerial and supervisory personnel roles in the laboratory performing high complexity testing.

In sum, the final regulations will preserve access to in-office testing and ensure accurate and reliable results by:

1. Categorizing semi-automated and automated instruments, simple kits and assays in the moderate complexity category;

2. Requiring *workable, flexible* personnel standards for both moderate and high complexity testing in that they do not mandate personnel that are simply not available in some communities and are not needed to assure quality testing;

3. Relying on a *cost-effective* three-pronged approach, which emphasizes a laboratory's participation in PT ***and*** the performance of QC and QA activities, in addition to appropriate personnel standards, to ensure quality testing as opposed to exclusively relying on the educational training of laboratory personnel.

In the report of the Energy and Commerce Committee, the Committee states that they intended for HHS to "develop flexible standards to make sure that proficiency testing, quality control, and *particularly personnel standards* are no greater than needed to assure accurate and reliable testing in the physician office laboratory setting." ASIM believes that HHS has developed the approach intended by the Committee. If you or your staff have any questions regarding ASIM's position on the final regulations, please contact Rich Trachtman at (202) 289-1700.

Sincerely,

Alan R Nelson MD

Alan R. Nelson, MD
Executive Vice President

american society of internal medicine

April 28, 1992

Mr. William Toby, Acting Administrator
Health Care Financing Administration
Department of Health and Human Services
Room 309 - G, Hubert Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Attention: **HSQ-176-FC: Medicare, Medicaid and CLIA Programs; Regulations Implementing the Clinical Laboratory Improvement Amendments of 1988**

Dear Mr. Toby:

On behalf of the American Society of Internal Medicine (ASIM), I'm pleased to submit the following comments on the Department of Health and Human Services' (DHHS) final rule implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA' 88). ASIM is a national medical society comprised of physicians who are recognized as specialists in internal medicine. Before detailing the specifics of ASIM's comments on the final rule, the Society would like to acknowledge the Health Care Financing Administration -- and the Centers for Disease Control (CDC) -- for their diligent efforts to implement CLIA 88. ASIM does not envy the massive task which Congress handed to the Department of not only developing implementing regulations but also of enforcing the standards. Overall, the Department, in partnership with CDC, did a remarkable job developing regulations that recognize the complexity of testing being performed in a laboratory, preserve access to physician office laboratory testing and ensure quality and accuracy of testing. ASIM has appreciated the opportunity to be a part of the process.

There are several key elements of the Department's approach to the final regulations that ASIM strongly supports and believes should be preserved in the final regulations. They are as follows:

A. *The commitment to maintain access to laboratory testing in a physician's office*: Many of the provisions of the final rule--most significantly the phase-in of the quality control standards, the phase-in for newly regulated laboratories of the requirement that laboratories participate in proficiency testing and the Department's willingness to waive the imposition of sanctions on newly regulated laboratories during the first inspection cycle--will give physicians operating in-office laboratories an opportunity to become educated about the new regulations so they can effectively comply with the standards and avoid harsh penalties. ASIM believes that smaller, less complex laboratories, many of which have never before been regulated, will have a more difficult time adjusting to the regulatory process and may

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initially be cited for condition level deficiencies, particularly those that do not pose immediate jeopardy (e.g. lack of an appropriate procedural manual). Such a massive regulatory initiative as CLIA 88 requires some time for adjustment and education. The flexibility that the Department has incorporated in the final rule will enable most physicians to continue to provide in-office testing.

B. *The complexity model:* The Department has developed a regulatory model in the final rule that will ensure that all available instruments, tests and kits are appropriately categorized as waived, moderate or high complexity. ASIM is especially pleased that the Department developed a way to regulate the complexity of the technology used to perform tests rather than simply regulating analytes as under the proposed rule. Without such an approach many of the analytes would have been categorized as highly complex because they are performed using highly complex instruments, tests, kits and assays. The model developed by the Department recognizes that most analytes, specifically in the specialties of chemistry, hematology, bacteriology, virology and immunology, are also performed with state-of-the-art automated and semi-automated instruments, simple kits and assays--specifically designed for the physician office laboratory setting--that allow tests to be performed more accurately and quickly with little chance of inaccurate results.

C. *The personnel standards for moderate and high complexity testing*: The final personnel standards for moderate and high complexity are flexible, cost-effective and will ensure quality testing (see detailed discussion below).

D. *The deletion in the final rule of the requirement that Level I (now called moderately complex) laboratories refer all abnormal screening tests to Level II (now called highly complex) laboratories*;

E. *The reliance on manufacturer recommendations, once approved by the Food and Drug Administration (FDA), for quality control*;

F. *The creation of the Clinical Laboratory Improvement Advisory Committee* to advise the Department and make recommendations on the technical and scientific aspects of CLIA; and

G. *The commitment to approve private non-profit accreditation programs, such as the Commission on Office Laboratory Accreditation (COLA), as quickly as possible* (see discussion later in the comments).

Final Personnel Standards for Moderate and High Complexity Testing

ASIM would like to take this opportunity to elaborate on the Society's strong support of the final personnel standards. The issue of personnel has been the most hotly debated issue throughout the evolution of the CLIA regulations. The task facing the Department has been to develop a regulation that ensures that personnel requirements are appropriate and sufficient for the

complexity of laboratory testing being performed. The final personnel requirements for moderate and high complexity testing meet this objective in a fair and reasonable way.

Under the *proposed rule* two provisions in the regulations would have resulted in the closure of most physician office laboratories (POL). First, a majority of the tests--even those analytes performed with methods especially designed for the POL setting that are very accurate and easy to use--would have been stringently regulated in the Level II category of testing (now called high complexity testing). Second, in the proposed rule, HCFA placed a heavy reliance on overly stringent personnel requirements for the laboratories performing Level II testing. ASIM argued that this approach would be extremely costly and unnecessary. For example, the proposed rule would have put most physicians owning in-office laboratories in the position of having to hire a medical technologist and pathologist full-time. As stated in the Society's comments on the proposed rule dated April 20, 1990, these requirements would have been cost prohibitive for most physicians.

Recall that ASIM maintained that HCFA should consider the advantages of a laboratory's performance of proficiency testing and quality control and quality assurance activities when developing effective regulatory mechanisms for ensuring quality testing. ASIM continues to believe that a combination of reasonable personnel standards, such as those contained in the final rule, participation in proficiency testing and documented quality control procedures for both moderate and high methods will ensure quality testing in the most cost-effective fashion. The final personnel standards are necessarily flexible as well. For example, a physician performing moderate complexity testing could decide to fill both the director and technical consultant roles in her in-office laboratory provided she has the appropriate training or experience. If a physician decides she wants to seek technical support to establish a quality control program she could hire a medical technologist or technician as a technical consultant. The technical consultant would only have to be accessible to the director and laboratory personnel on an as needed basis. Group practices owning in-office laboratories are likely to hire a medical technologist or technician to be the technical consultant depending on the size of their laboratory practice and the affordability and availability of laboratory personnel. Solo practicing physicians in rural areas, however with much smaller laboratory operations, are likely to assume the role of technical consultant and director provided they have the requisite training or experience required. For these physicians hiring another individual for the technical consultant would be cost-prohibitive and unnecessary given the smaller scope of testing and size of the laboratory operation.

The proposed regulation, if enforced, would have been unworkable in that many laboratories, specifically those laboratories in rural areas and certain urban areas, simply do not have access to the highly trained personnel as would have been required under the proposed rule. To illustrate, the American Society of Clinical Pathology has published articles which indicate there is a serious shortage of trained laboratory personnel--namely medical technologists--in this country. Specifically, a survey conducted by ASCP (Barbara Castleberry, PhD, MT; Alma Kuby, MBA; and Barbara Bryant, PhD; "Wages and Vacancy Survey of Medical Laboratory Positions in 1988: Part II", Laboratory Medicine, June 1989) found that 88 percent of the laboratory managers surveyed indicated a shortage of medical technologists in their area.

In a broader context, ASIM has maintained that the precision of the instrumentation used in many laboratories doing moderate complexity testing and the simplicity of the test methods eliminate the necessity to place a heavy reliance on personnel standards. This is especially true in the POL setting. To illustrate, a 1988 study conducted by Dr. Amin Nanji; Raymond Poon, Ph.D and Irwin Hinberg, PhD ("Physician Office Analyzers: Do They Satisfy Medically Useful Criteria for Analytical Performance of Laboratory Tests?", Arch Pathol Lab Med, Vol 112, July 1988) concluded that automated "physician analyzers do satisfy the medically useful coefficients of variations (CVs) criteria, i.e. the precision obtained by both the technologist and nontechnical personnel either equaled or exceeded the precision requirements set by physicians". Technical and nontechnical personnel were evaluated for their performance of AST, bilirubin, cholesterol, creatinine, glucose, hemoglobin, potassium, sodium, triglyceride and urea nitrogen tests. A 1986 study conducted by Robert Crawley, MT (ASCP); Richard Belsey, MD; Darrell Brock, DrPH and Daniel Baer, MD ("Regulation of Physicians' Office Laboratories", JAMA, Jan 17, 1986, Vol 255, No. 3) found that state regulation in Idaho, requiring each office laboratory to comply with quality assurance guidelines and to participate in a proficiency testing program, resulted in a marked improvement in the proficiency level of office laboratory testing in Idaho. The study also concluded that stringent personnel standards are probably not necessary for physician office laboratories provided other measures to ensure quality testing, i.e., proficiency testing and quality controls, are instituted.

The problems that the proposed rule would have created have been significantly reduced in the final rule. With only a few exceptions, HCFA has appropriately categorized those semi-automated and automated instruments, easy to use kits and assays traditionally used in a physician office laboratory in the moderate complexity category. In conjunction with the shift of tests from the high (formerly Level II) to moderate complexity category (formerly Level I), HCFA strengthened the personnel standards for the moderate complexity category. The final personnel standards for both moderate and high complexity testing are flexible so as not to mandate personnel that are simply not available in some communities. The final regulations strike a balance between appropriate personnel standards, participation in proficiency testing and the performance of quality control and assurance activities in ensuring quality laboratory testing. The final personnel standards necessarily allow a physician with the appropriate training or experience to direct a laboratory and/or serve as a technical consultant. The end result is that the final personnel standards should ensure quality testing in the most cost-effective way while preserving access to in-office testing.

Further Clarification of the Moderate Complexity Personnel Standards

Most recently, resulting from the urging of staff both at the Health Care Financing Administration (HCFA) and CDC, the medical profession has been working closely together to further clarify provisions in the final rule. Specifically, the working group has focused its attention in the following areas:

A. the feasibility and practicality of developing unified standards for continuing medical education (CME) programs as detailed in Section 493.1405 (b)(2)(ii)(B); and

B. Ways that physicians, designating themselves as the director and/or the technical consultant/supervisor of laboratories performing moderate/high complexity testing can demonstrate they have the experience required to fill these roles in a laboratory.

Two months ago, the American Medical Association (AMA) convened all interested medical specialty societies, including ASIM, to discuss these issues. The group met in-person on two occasions and participated in a conference call in late March. Two sub-groups were formed--one to further develop thoughts on the CME option for those physicians that want to be laboratory directors but do not have the requisite training or experience to direct moderately complex laboratory testing, and another on issues related to how physicians can document their experience.

How Can Physicians Document That They Have the Requisite Residency Training or Experience?

ASIM, the AMA and other national specialty society organizations recognize that inspectors will need flexible instructions to help them determine whether a physician has the requisite experience to be a director or serve as the technical consultant/technical supervisor of laboratories performing moderate or high complexity testing. HCFA has asked the medical profession for guidance on this issue. ASIM believes that the best way for physicians to demonstrate that they have the requisite experience would be to require physicians to sign a statement which indicates that they or their designated laboratory director has the one/two years experience or training required to direct a moderate/high complexity laboratory or the CME course which can be taken to qualify as the director of a moderate complexity laboratory. If an inspector or HCFA suspects that a physician does not have the requisite training or experience supervising or directing moderate/high complexity testing then the physician should provide additional documentation in any of the ways listed below. This is not meant to be an exhaustive list. Documentation options could include:

1. successful participation in a proficiency testing program;

2. accreditation by private non-profit accreditation programs, such as the Commission on Office Laboratory Accreditation (COLA), or some other approved non-profit, private accreditation program;

3. Medicare billing for laboratory tests in question;

4. completion of training programs such as those conducted by the manufacturer of the equipment being used by the physician;

5. a quality assurance log book in which dates are noted with patient records;

6. a bill of sale for laboratory testing equipment;

7. a statement from a qualified laboratory director or technical consultant which indicates that the physician performed or supervised laboratory testing under the supervision of the director or consultant for one year; or

8. a certificate indicating that the physician has completed 20 hours of approved CME meeting the requirements for laboratory director.

These are just some of the ways that a physician could further document that he/she has the requisite one/two years experience supervising moderate/high complexity testing to fill the director role. Physicians designating themselves as the technical consultant/supervisor of laboratories performing moderate/high complexity testing could also rely on these forms of documentation to demonstrate that they meet the experience necessary to qualify as the technical consultant. ASIM believes that these comments will assist the Department in further developing guidelines for inspectors and should be incorporated as "probes" in final survey process and interpretive guidelines that will be given to field inspectors. ASIM urges the Department to include these comments in the final inspector guidelines as well as our comments on the draft guidelines contained in the Society's April 10 letter to Ms. Judy Yost.

ASIM has given some thought to ways in which physicians could demonstrate that they have laboratory training during their residency equivalent to the 20 hours of CME to be a director of a moderate complexity laboratory or one year of laboratory training during medical residency in the specialty of subspecialty of testing being supervised to qualify as the technical consultant of a moderate complexity laboratory. Additionally, under the final regulation, physicians could qualify as a director or technical supervisor in a highly complex laboratory if they have one year of laboratory training during their medical residency (physicians must also have at least 6 months of experience in the appropriate subspecialty to qualify as the technical supervisor). To demonstrate the appropriate training during medical residency, ASIM believes that physicians should be required to provide HCFA a written statement from the director of their medical residency program stating that they have had the requisite training to serve as the director of a moderate/high complexity laboratory and/or the technical consultant/technical supervisor in their specialty or subspeciality.

Continuing Medical Education (CME) for Moderate Complexity Testing

Allowing physicians to acquire 20 hours of continuing medical education (CME) to fill the role of director of a laboratory performing moderate complexity testing is an excellent and appropriate option to make available to physicians who do not have the one year of experience supervising moderate complexity testing or are not offered the one year laboratory training during residency. The AMA, ASIM and several other national medical specialty societies have worked diligently to provide HCFA and CDC with additional guidance on the CME option. Specifically, the working group plans to continue to work on the development of a core curriculum with specialty specific modules with which to accredit CME programs for the laboratory director function for moderate complexity laboratories. ASIM supports the core curriculum oeveloped by the working group which would more than provide a physician with the knowledge and skills required to qualify as a director of a moderately complex laboratory **(see Attachment A)**.

Additionally, under the final regulations, there is not a CME option for physicians to qualify as a technical consultant for moderate complexity testing if they do not have the requisite training or experience. *ASIM believes that physicians wanting to serve as technical consultant should have a CME option available to them if they do not have the requisite training or experience in moderate complexity testing*. As previously discussed, many physicians will be required to fulfill the function of the technical consultant as well as the laboratory director, particularly in those areas where qualified consultants are not readily available or in cases where a physician is performing such a low volume of testing that he/she cannot afford to hire a technical consultant. ASIM believes that the core curriculum developed by the working group is a good example of curriculum that would adequately train a physician to fill both the role of director and technical consultant of a moderate complexity laboratory. The curriculum is particularly sensitive to the scientific and technical aspects of the responsibilities of the technical consultant rather than the director. One would presume that the director's role of supervision would naturally follow if the director has the technical skills to understand and implement a quality control and quality assurance program.

ASIM believes that physicians will need to participate in a number of CME programs to acquire the full 20 hours (currently there are no single programs available that are 20 hours and ASIM does not believe there are likely to be programs developed in the future). For example, the College of American Pathologists (CAP), and the American Academy of Family Physicians (AAFP) will be offering CME programs of less than 20 hours. ASIM envisions that a physician may participate in a CME program that focuses on the responsibilities of the laboratory director and may also participate in a CME program focusing exclusively on proficiency testing to achieve the full 20 hours. For this reason, ASIM believes that a mechanism should be developed to assist accredited providers to supplement rather than duplicate the course material to avoid forcing physicians to take three or four programs which cover the same material just to achieve the required 20 hours.

Accreditation of CME Courses

CME courses recognized by HCFA for credit toward the 20 hours of CME for the director and technical consultant (should HCFA recognize CME credit for this position as recommended by ASIM) should meet the responsibilities of the director and technical consultant as specified in the CLIA regulations. In order to exercise quality control of the required 20 hours of CME, HCFA should recognize courses which are:

1. Designated AMA PRA Category 1 credit by an ACCME accredited sponsor; or
2. Approved for prescribed credit by the American Academy of Family Physicians; or
3. Approved for American Osteopathic Association (AOA) credit by the AOA.

and

4. *HCFA should recognize accreditation by non-profit, private accreditation programs, such as the Commission on Office Laboratory Accreditation (COLA), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the College of American Pathologists (CAP), which achieve "deeming" authority as fulfilling the experiential requirements for the director provided that the physician-director has gone through an extensive inter-active educational process that results in meeting all the standards of the non-profit, private accreditation program, for laboratory performance, is verified by an on-site inspection and is accompanied by a certificate of accreditation.* For example, COLA provides laboratory directors a self-assessment and education program whose goal is to improve their understanding of the elements that constitute quality laboratory performance in the physician office laboratory setting. COLA provides written materials for self-study for physicians in areas found to be deficient in the self-assessment process, and ultimately inspects the laboratory to confirm that the director has placed the elements of quality performance in use in the laboratory.

Finally, ASIM believes it will take some time for CME courses to be developed and to become available to physicians. After which physicians, requiring CME, will need to enroll in and complete a CME program. For this reason, ASIM believes that the effective date for the CME credit for the director and technical consultant (if approved by HCFA) and the training and experience requirement for both the director and technical consultant should be set at Sept. 1, 1994. There is some discrepancy in the final rule as to when the effective date actually is. In the preamble, it states Feb. 28, 1993 yet the regulatory language states August 2, 1993. ASIM understands that this technical inconsistency will be corrected.

Microscopic Urine and Vaginal Wet Mount When Personally Performed by a Physician

ASIM believes that microscopic urine and vaginal wet mount tests should be waived only when personally performed by the physician as part of a physical examination. ASIM understands that these tests have been placed in the moderate complexity category because they do require some training to perform. However, ASIM strongly believes that physicians receive considerable training during medical residency to perform these tests and are more than qualified to do so. ASIM has heard from several internists across the country performing very basic testing (primarily waived) and that the microscopic urine is the single test that shifts them from the waived to the moderate complexity category. Unfortunately, the additional costs of compliance with CLIA to perform this one test (e.g. a registration fee of $350, participation in proficiency testing and most significantly the compliance fee) would be cost-prohibitive for many physicians to continue providing this test to their patients. Often physicians do not even charge for the performance of a microscopic urine and consider it a part of the physical exam. The revenues associated with the performance of this test are simply not sufficient to cover the costs of providing the test to patients if it is subject to moderate complexity regulations. Many physicians would be forced to stop providing this test to their patients. Similar arguments apply to vaginal wet mounts. Obviously, this would seriously jeopardize the prompt delivery of patient care for people suffering from urinary or vaginal infections.

Unannounced Inspections

Probably the biggest issue that continues to be of significant concern to ASIM is the cost of inspections and the Department's plan to conduct unannounced inspections. ASIM strongly urges the Department to add some flexibility to the program and allow the performance of announced inspections at least in those laboratory settings where direct patient care is being provided--namely physician office laboratories (POLs). While ASIM understands that HCFA has traditionally conducted inspections on an unannounced basis, particularly in the nursing home setting for purposes of Medicare certification, ASIM believes that regular unannounced inspections of physician office laboratories are unnecessary in most situations and will only increase the inspection fee, and more significantly, needlessly disrupt patient care. ASIM does believe, however, that laboratories with recognized performance problems or those that are the subject of a public complaint should be inspected on an unannounced basis.

Testing performed in a POL setting is unique. Unlike the operations of a commercial laboratory, not only does a physician either perform or supervise lab testing, he/she also provides direct patient care. If an inspector were to show up unannounced for an inspection, the physician's care of his or her patients would almost always be disrupted while the physician dealt with the concerns of the inspector. Additionally, POLs commonly make use of part-time laboratory personnel, especially if the volume of testing is low. The inspection may occur when tests or procedures are not being run. In some cases the physician or laboratory personnel may not be in the office or the office may be closed entirely when the inspector comes to perform an unannounced inspection. The inspector would then be forced to return to the laboratory at another time which would add additional costs to the program. ASIM is concerned that these inefficiencies will increase substantially the cost of inspections. Although the issue of compliance fees is the subject of another final regulation, ASIM is concerned that the cost of inspections will be excessive and financially prohibitive for some physicians operating physician office laboratories. Any effort that the Department can take to reduce the cost of inspections is desirable. This continues to be a top priority for ASIM. ASIM believes that announced inspections of the physician office laboratory will be more cost-efficient.

ASIM would like to refer the Department to Section 353 (g) of the CLIA statute that grants the Secretary the discretion to conduct "announced or unannounced inspections". Additionally, the Report of the House Committee on Energy and Commerce on CLIA 88 (House of Representatives Report #100-899, page 32) states that the Committee "expects the Secretary to have many of these inspections conducted on an unannounced basis....". "The Committee also expects the Secretary to take measures to insure that all inspections--unannounced in particular--are conducted with due consideration for the potential of inappropriate interference or disruption of the laboratory or the physician office. Inspectors should, for example, be attentive when inspecting a physician office laboratory to the needs of patients awaiting care." ASIM believes that the CLIA statute clearly grants the Department the authority to conduct announced inspections. The Committee report language demonstrates that Congress believes that the Department should exercise serious caution so as not to disrupt patient care when conducting inspections in the physician office laboratory setting.

ASIM believes that the only way to avoid the disruption of patient care is to conduct *announced* inspections. ASIM believes that giving physicians advanced notification that an inspection will occur will give physicians an opportunity to rearrange their patient schedules so as not to have patients waiting to be cared for while the physician assists an unexpected inspector. ASIM understands that HCFA's intent to conduct unannounced inspections is to ensure that laboratories aren't scrambling to meet CLIA requirements at the last minute, just before the inspector arrives. However, ASIM seriously doubts that physicians with office laboratories would be inclined to wait until the last minute to comply with CLIA standards or would be able to develop the extensive documentation required within a short period of time. Rather than serving as an advanced warning to physicians as to when they are to be inspected so that they can comply with the standards at the last minute, notice would give physicians an opportunity to adjust their patient schedules to accommodate the inspector's needs.

ASIM urges the Department to contact those states–Pennsylvania, Illinois, Washington and Maryland–that have experience in inspecting the physician office laboratory setting. These states have evaluated and *rejected* unannounced inspections of POLs for the reasons detailed in these comments. ASIM believes that these states could provide the Department with practical input and guidance on the issue of announced vs. unannounced inspections.

Finally, ASIM believes that given the far-reaching implications of CLIA 88 on the physician community, it is critical that physicians know that they must comply with the new standards and that inspectors will give them the appropriate feedback and technical assistance to accomplish this. If the Department conducts announced inspections physicians are likely to more readily accept that they must comply with the new quality assurance program and are less likely to view the inspection process as an intrusion into their practice. Unannounced inspections have a tone of a presumption of guilt before an inspection actually takes place. The physicians often resent programs that imply that the quality of care they provide is questioned without any evidence of support for such a presumption. Obviously, a more cooperative and friendly inspection process–which would be more characteristic of an announced rather than unannounced inspection–is better for physicians and the inspectors.

Costs of Compliance

ASIM continues to be concerned about the potential effects of the regulations on the ability of physicians to continue to providing testing in their office, specifically the costs of inspections. In addition to the costs of inspections, physicians operating in-office laboratories performing non-waived testing will be faced with additional costs associated with meeting the quality control and quality assurance standards and the cost of participation in proficiency testing. While ASIM is pleased that the Department has made every effort to develop standards that ensure quality testing in a cost-effective fashion, it is imperative that the Department, in conjunction with representatives of the physician office laboratory community, continues to evaluate the effects of these costs on access to in-office testing. ASIM hopes to work with the Department to ensure that the regulations are cost-effective and specifically to develop ways to reduce the cost of inspections.

Approval of Non-Profit Private Accreditation Programs and State Licensure Programs

ASIM strongly urges the Department to make every effort to approve private, non-profit accreditation programs, such as the Commission on Office Laboratory Accreditation, as soon as possible so that the private sector can assist HCFA in certifying laboratories, and more importantly, so that physicians will have the private sector alternative available to them as intended by Congress. Additionally, until HCFA approves state licensure programs, physicians with laboratories in states with their own licensure programs will be subject unfairly to two sets of regulations and more importantly two sets of compliance fees.

Again, ASIM appreciates the opportunity to respond to the final regulations implementing CLIA 88. Your Department has done a remarkable job. ASIM looks forward to working closely with the Department throughout the implementation and certification process. Obviously, given the immense educational process that will be necessary to ensure a smooth and fair implementation of the CLIA requirements, it will take considerable cooperation among the medical profession, the Department and state agencies. ASIM stands ready to work with you and your staff.
If you have any questions, regarding ASIM's position on the final rule, please contact Tammy Zinsmeister at (202) 682-8616.

Sincerely,

Eugene S. Ogrod MD

Eugene S. Ogrod, MD
President

Attachment A

PROPOSED CORE CURRICULUM FOR LABORATORY CME COURSES

ASIM believes that physicians, who do not meet the one year training or experience requirements necessary to be a director of a moderate complexity laboratory, should acquire through a CME program, or *combination of programs*, knowledge and skills in four general areas:

1. Physical plant:. Specifically, physicians should acquire knowledge and skill to enable him/her to:

   - determine appropriate space and environmental needs;
   - identify safety needs;
   - identify hazards; and
   - establish policies and procedures for quality control and quality assurance.

2. Testing systems and equipment: Specifically, physicians should acquire knowledge and skill to enable him/her to:

   - verify or establish performance specification for each method--accuracy, precision, analytical sensitivity and specificity;
   - establish the reportable range of patient test results;
   - successfully conduct proficiency testing;
   - to establish and follow quality assurance mechanisms to monitor and evaluate overall quality of the testing process;
   - to establish remedial action policies and procedures;
   - to employ and maintain a system for patient preparation, specimen collection, identification, preservation, transportation, processing, and accurate result reporting; and
   - evaluate new test systems.

3. Laboratory Personnel: Specifically, physicians should acquire knowledge and skill to enable him/her to:

   - select qualified personnel to perform testing procedures, provide technical consultation and provide clinical consultation;
   - determine job responsibilities;
   - manage and provide supervision to laboratory personnel; and
   - establish and follow quality control and quality assurance mechanisms for individual and group performance.

4. Written policies, procedures, and individual performance responsibilities: Specifically, the physician should acquire knowledge and skill to enable him/her to:

   - write, evaluate, and revise manuals on policies, procedures and performance responsibilities.

STATE OF FLORIDA
DEPARTMENT OF HEALTH AND REHABILITATIVE SERVICES

April 29, 1992

United States House of Representatives
Committee on Energy and Commerce
Subcommittee on Oversight and Investigation
2323 Rayburn Building
Washington, D.C. 20515

RE: Addendum to CLIA 88 Comments

Dear Sirs:

Information has recently come out that FDA has been conducting a survey of physician office laboratories (POL) in five or six states regarding potential problems as related to instrument and kit testing accuracy. The focus, as I understand it, is how well is the POL following the manufacturer's directions for calibration, quality control and performance of the so called "black box" operation.

I have talked with several states which have been involved with the study and the primary problem is that operators do not realize they are having problems. Their primary contact is the manufacturer's representative if they think they are having a problem. Some other observations are:

1. Several instruments should be calibrated more frequency than the manufacturer recommends;

2. Some need more preventative maintenance than specified;

3. A significant number of operators are not running controls and documentation of control frequency and values is sparce.

It is my understanding that the final report of these studies is to be sent to FDA next week (May 4th) by the participating states. Will FDA share these findings with HHS, HCFA, your office and the states? Should these findings be evaluated before FDA and HIMA are permanently installed as quality control authorities? I heard the April 13 meeting between the two groups did not solve any problems.

Please add these comments to my letter which was mailed to your office last week.

Sincerely,

Laura M. Phillips

Laura M. Phillips, M.A.
Biological Administrator
Laboratory Licensure Section

2727 MAHAN DRIVE • TALLAHASSEE, FLORIDA 32308

Commonwealth of Pennsylvania

DEPARTMENT OF HEALTH

BUREAU OF LABORATORIES

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Pickering Way & Welsh Pool Road
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April 23, 1992

Ms. D. Ann Murphy
U.S. House of Representatives
Committee on Energy & Commerce
Subcommittee on Oversight & Investigation
Room 2323 Rayburn Building
Washington, DC 20515

Dear Ms. Murphy:

Previously I've sent information on some of the kits on which we've taken action along with a small study on proficiency testing data of various immunological tests. Enclosed are some package inserts which I have available and a compilation of some manufacturers' comments concerning quality control.

The problem of quality control is one with which we are struggling in terms of strength of positive control material, selection of a negative control and a frequency of performing quality control.

Often times the positive control yields a frank positive reaction while many times positive patient samples produce less intense reactions. Experience has shown us that many individuals use the positive control reaction as a reading standard. If the laboratorian tests a large number of samples, he/she may recognize this problem and the error rate should decrease. However, if the laboratorian performs few tests, over a long period of time, the problem may go undetected. We see this later scenario in physician office laboratories.

Negative control material range anywhere from a material similar, but not identical to the positive control to a sterile swab. This material is intended to test the system for cross reactivity to prevent a false positive reaction. The selection or the design of the negative control must adequately challenge the specificity of the system. In some of the newer systems which are monoclonal in design, the need for this material is questioned because cross reactivity is minimized if not eliminated.

Frequency of quality control has been traditionally set at each day of use for many tests. This prescription does not take into account the stability of the test system. The same frequency is required for a system having an in-use shelf life of 6 months as does one have an in-use shelf life of only 1 month. Some of the current systems require this level of control whereas others do not.

As test systems become more non-biologic in design, the stability increases dramatically with a corresponding decrease in need to perform quality control. The problem we have is determining a reasonable frequency for performing quality control on the newer systems without compromising patient results.

We looked to the package inserts for some answers to our problems and found great variance. Some manufacturers ignore the issue, others simply indicate that it's good laboratory practice to perform quality control with materials which they may or may not provide, while others stipulate a more traditional approach. For some, the rationale for their quality control scheme appears to be based on an administrative/legal decision founded on laboratory regulations at the time of introducing the test into the marketplace while others base their scheme on science, i.e., stability of the test, possibility of interfacing substances, etc. Therefore, it is possible for two manufacturers' products, both identical in technology and purpose, to have two different quality control schemes. A regulatory reliance on the manufacturers' guidelines may lead to a wholesale reduction in the frequency of quality control which may not be scientifically justified.

It is apparent that current regulations require an approach to quality control which has not kept pace with the advancements in technology. The question remains - Is this approach necessary to assure quality results in all laboratory settings which process different numbers of specimens by individuals possessing different levels of laboratory training?

Sincerely,

Ron Neimeister

Ron Neimeister, MPH Director
Technology Transfer and
Safety Program

Enclosures: 38 package inserts
1 summary

cc: John D. Dingell, Chairman
Subcommittee on Oversight and Investigations

Studies Conducted at
Bureau of Laboratories
Pennsylvania Department of Health

Bacteriology Kits

Proficiency testing of physician office laboratories in Pennsylvania revealed that their ability to detect Group A beta streptococci is directly related to the systems used. False positive rates of 37% and 45% were recorded for two kits each being promoted (and cleared for use by the FDA) as being capable of detecting Group A beta streptococci. The problem with the kits was that positive results from any beta hemolytic organism was interpreted as Group A beta strep. One of the manufacturers has since changed the labeling of the kit and package insert. (See the information on Isocult) The other manufacturer is in Finland and the packing/insert labeling change took a little longer. (See MTC correspondence). Another kit for detecting Group A beta strep produced positive results when it came in contact with a paper towel. This test is no longer on the market and the manufacturer NEVER had FDA premarket clearance for the product. This particular matter is in the hands of the FDA.

Test for Food Sensitivities

We received reports from our laboratory examiners that a cytotoxic test for food sensitivities was being used in a physician's office. This technology has not been cleared for use by the FDA. Based on this fact and the lack of any scientific data from the manufacturer, we could not approve its use on residence of Pennsylvania. See letter to Roger Deutsch.

Chemistry Analyzer

A manufacturer attempted to introduce an analyzer into Pennsylvania with accompanying pipetting devices. Due to the inaccuracy of the pipettes and the refusal of the manufacturer to change pipettes, the analyzer was not permitted to be used in the State. (See Technical Notes - Inappropriate Use of One-Piece Pipettes)

Cholesterol - Whole Blood Tests

The kit cited in the memo - LipoScan TC was not approved for use on residence of Pennsylvania. A similar cholesterol kit, Chemcard Whole Blood Cholesterol Test, suffered with the same problems as the LipoScan kit and was also not permitted to be used in Pennsylvania. Both kits were cleared for use by the FDA.

Built-in controls used each time test is performed

The regular use of a positive control is advised to evaluate day to day consistency Confidot Plus strep

Use Remel Staph Positive Control each day tests are run. Use Remel Staph Latex Negative Control each day tests are run.
Remel

Good laboratory practice recommends the daily use of controls to ensure proper kit performance. Positive and negative controls are available for use with the kit hCG Urine Abbott

Run quality control once daily under normal circumstances it will become apparent in day-to-day testing if the reagent fails to operate properly. Staphaurex

For best results, performance of reagent strips should be confirmed by testing known negative and positive specimens or controls whenever a new bottle is first opened. Negative and positive specimens or controls may also be randomly hidden in each batch of specimens tested. Ames Multistix

No QC Gastroccult Isocult for trich and candida Staph GC

No frequence AccuCheck II

Good laboratory practice indicates running positive and negative controls to ensure that the reagents are performing properly.

a. Controls may be run using the procedure described in Section 10 AccuPoint Toxo Strep Rubella

b. Materials which are available from Quidel Preg Materials available from Ventrex

c. can be confirmed with commercially available control samples
Quidel Allergy Screen
Quidel Ovulation test

Quality control for this procedure consists of following good laboratory techniques and insuring that reagents have been properly stored and specimens handled according to instructions. Prepared suspensions of leukocytes in urine are recommended for daily quality control use in leukocyte testing. Boehringer Chemstrip

From time to time it is advisable to check the performance Reveal

Run known positive specimens to confirm the reactivity of the test.
One-Step hCG Wampole

Check performance by inoculation of pure broth cultures of control organisms. The following quality control organisms are recommended.
Uri-kit

MICHIGAN'S COMPREHENSIVE BREAST AND CERVICAL CANCER CONTROL PROGRAM

YEAR TWO REAPPLICATION

EXECUTIVE SUMMARY

Implementation of Michigan's comprehensive statewide breast and cervical cancer control project is well underway. Under the guidance of the Michigan Department of Public Health's (MDPH) Cancer Section, the project is increasing the availability and accessibility of screening services for low-income women across the state. Project staff are heavily involved in the development of statewide policies and regulations intended to improve the quality of mammography available throughout Michigan. Efforts on other quality-assurance fronts are proceeding as well. The implementation of education programs directed both to women and their health care providers has begun, with advice from a variety of expert advisors from across the state. Under this project, a strong surveillance and evaluation component is being implemented to monitor the impact of this comprehensive, coordinated approach to reduce mortality due to breast and cervical cancer.

In Year One, the Michigan Breast and Cervical Cancer Control Project began offering screening and follow-up services for breast and cervical cancer in 11 local public health agencies serving 27 counties in Michigan. Contracts with another seven local public health agencies will be entered into before the end of Year One. After 12 months of offering screening services, these 18 agencies will have enrolled approximately 16,000 women with limited or no financial resources into a system of care which not only provides regular, age-appropriate screening and education, but also assures that follow-up services are provided if needed.

Depending on the availability of sufficient federal funds, MDPH will initiate a breast and cervical cancer screening and follow-up project in every county in Michigan within the second year of the Cooperative Agreement. It should be noted that this Year Two reapplication does NOT include a request for a waiver on the requirement in Public Law 101-354 that screening and follow-up services be available throughout the state.

This application requests $11,786,573 of federal funding to be matched by $3,830,309 (33%) of in-kind contributions to support the second-year costs of a comprehensive, statewide breast and cervical cancer program. This funding will support a screening and follow-up site in each of Michigan's 83 counties, serving up to 36,000 low-income women by the end of Year Two.

By the end of Year Two, all required components of the comprehensive breast and cervical cancer control project will be addressed, and all federal minimum requirements and guidelines will be met or exceeded.

The Cooperative Agreement for Breast and Cervical Cancer Control from the U.S. Centers for Disease Control (CDC) has enabled MDPH to increase and improve its already substantial activities in quality assurance, professional education, coalition building, and surveillance to assure a comprehensive, coordinated, high-quality statewide system for control of breast and cervical cancer. It also has enabled MDPH to bring life-saving screening, diagnostic, and treatment services to a significant number of low-income women throughout Michigan.

Investigation and Compliance Section
Division of Radiological Health
Michigan Department of Public Health

Following is a partial summary of our inspection results for mammography machines and facilities inspected in 1988 through early November.

	Hospitals	Radiology Offices	Medical Offices
Machines inspected:	43	31	21
Machines with poor image quality[1]: (phantom image)	10 (23.3%)	11 (35.5%)	12 (57.1%) = 35.9%
Machines with high radiation exposures[2]:	2 (4.7%)	3 (9.7%)	3 (14.2%)
Machines with high patient mean glandular doses[3]:	4 (9.3%)	1 (3.2%)	2 (9.5%)
Machines with one or more of the above problems:	14 (32.6%)	14 (45.2%)	14 (66.7%)
Machines for which less than optimal conditions were noted, other than those problems tabulated above[4]:	16 (37.2%)	9 (29.0%)	10 (47.6%)
Total machines with either poor image quality, high patient exposure at skin entrance, high patient mean glandular dose, or other condition resulting in unnecessary radiation to patients or in suboptimal image quality:	20 (46.5%)	15 (48.4%)	16 (76.2%)

[1]The image of an ACR accreditation breast phantom used by our staff did not appear to meet the minimum requirements of the ACR in terms of the number and size of observable test objects.

[2]Radiation exposures at skin entrance exceeded the upper Standard of Care limits established by our Radiation Advisory Board.

[3]Mean glandular doses exceeded the upper recommended limits of 0.1 rad, 0.2 rad, and 0.4 rad per view for film imaging without a grid, film imaging with a grid, and Xerox imaging, respectively.

[4]Examples of suboptimal conditions noted during our inspections include the following: half-value layer of x-ray beam too high, film processing temperature too low, poor choice of film type, processor rollers need cleaning (film shows roller marks), inconsistent radiation output, film appeared darker than typically observed, film appeared lighter than typically observed, image degraded due to grid lines caused by a broken reciprocating grid, use of a general purpose machine for film mammography, dirty intensifying screens, unnecessarily high radiation exposure (but still within limits), and film improperly loaded upside down in cassette (emulsion side away from screen).

Investigation and Compliance Section
Division of Radiological Health
Michigan Department of Public Health

Following is a partial summary of our inspection results for mammography machines and facilities inspected during the period from December 1990 through August 1991 (pre full implementation of P.A. 52)

	Hospitals		Radiology Offices		Medical Offices		Total Machines	
	ACR	Non-ACR	ACR	Non-ACR	ACR	Non-ACR	ACR	Non-ACR
Machines inspected:	100	65	101	75	26	65	227	205
Machines with poor image quality[1]: (phantom image)	9 (9.0%)	6 (9.2%)	12 (11.9%)	19 (25.3%)	5 (19.2%)	20 (30.8%)	26 (11.5%)	45 (22.0%)
Machines with high radiation exposures[2]:	9 (9.0%)	6 (9.2%)	7 (6.9%)	14 (18.7%)	1 (3.8%)	10 (15.4%)	17 (7.5%)	30 (14.6%)
Machines with high patient mean glandular doses[3]:	6 (6.0%)	7 (10.8%)	6 (5.9%)	8 (10.7%)	1 (3.8%)	3 (4.6%)	13 (5.7%)	18 (8.8%)
Machines with one or more of the above problems:	18 (18.0%)	13 (20.0%)	19 (18.8%)	31 (41.3%)	6 (23.1%)	25 (38.5%)	43 (18.9%)	69 (33.7%)

[1]The image of an ACR accreditation breast phantom used by our staff did not appear to meet the minimum requirements of the ACR in terms of the number and size of observable test objects.

[2]Radiation exposures at skin entrance exceeded the upper Standard of Care limits established by our Radiation Advisory Board.

[3]Mean glandular doses exceeded the upper recommended limits of 0.1 rad, 0.2 rad, and 0.4 rad per view for film imaging without a grid, film imaging with a grid, and Xerox imaging, respectively.

In addition to the problems described above, other suboptimal conditions were also noted during our inspections and included the following: half-value layer of x-ray beam too high, inaccurate indication of kilovoltage, film processing temperature too low, poor choice of film type, processor rollers need cleaning (film shows roller marks), inconsistent radiation output, film appeared darker than typically observed, film appeared lighter than typically observed, image degraded due to grid lines, dirty intensifying screens, poor quality control over image processing, long exposure times, and large effective focal spot sizes.

ACR: American College of Radiology accredited machines
Non-ACR: Machines not accredited by the American College of Radiology

10-31-91

Michigan's Cancer Screening Program for Women

The Problem:

More than 1,500 Michigan women die every year from breast cancer and another 150 women will die from cancer of the cervix. Many of these 1,650 deaths are preventable. In fact, nearly half of the deaths from breast cancer, and virtually all the deaths from cervical cancer, can be prevented through yearly screenings and appropriate medical follow-up of any abnormalities.

All women should be screened for breast and cervical cancers throughout their lifetimes. It is especially important to increase screening of older women, minority women, and low-income women because they are least likely to get mammograms and Pap smears, and most likely to die from breast or cervical cancer.

What Can Be Done?

In July 1991, the Michigan Department of Public Health received a five-year, $3 million-per-year grant from the U.S. Centers for Disease Control under a new federal law (P.L. 101-354, adding the Title XV amendment to the Public Health Service Act), to implement a women's breast and cervical cancer control program. With these funds, local health departments in Michigan are now able to give low-income women access to life-saving cancer screening services and follow-up care.

Services Available:

Through these new local public health programs, women aged 40 and older can receive:

- Clinical breast exams;
- Pap smears;
- Pelvic exams;
- Screening mammograms; and

- Appropriate referrals to community providers for follow-up of abnormalities, if necessary.

Depending upon a woman's medical need and her financial and insurance status, federal grant funds also may provide:

- Diagnostic mammograms;
- Colposcopy services; and
- Colposcopy-directed biopsy services.

Who Is Eligible?

This new federal grant program is targeted especially at low-income women aged 40 and older. With these funds, health departments can provide screening services at no cost to uninsured women whose incomes are at or below the federal poverty level; and reduced-cost services for uninsured women whose incomes range up to 250 percent of the federal poverty level.

Women with insurance also can be served by this program, but their insurer will be billed for services provided. If their insurance does not cover one or more of the services, they may be eligible for free or reduced-cost services, depending upon their income. Women with the ability to do so will be encouraged to seek screening and follow-up services from their private physicians.

Where Are These Services Available?

As of March 1992, eleven local health departments serving 29 Michigan counties are offering these services, and additional agencies are scheduled to begin offering them by mid-1992. Depending upon the availability of additional federal funds, expansion to all areas of the state is expected by 1994.

Where Can I Get Information?

For information about the location of participating local health departments, please call the Michigan Health Promotion Clearinghouse Hotline at 1-800-537-5666. For more information about becoming involved as a provider of services for local Breast and Cervical Cancer Control programs, call (517) 335-9161.

MICHIGAN'S TITLE XV BREAST AND CERVICAL CANCER CONTROL PROJECT SITES

COHORT #1

Agency	Number of Screening Sites	Location of Screening Sites	First Year Client Caseload
DISTRICT HEALTH DEPARTMENT #3 - (616) 547-6523			1,250
Antrim County	1	Bellaire	
Charlevoix County	1	Charlevoix	
Emmet County	1	Petoskey	
Otsego County	1	Gaylord	
DISTRICT HEALTH DEPARTMENT #4 - (517) 358-4507			1,808
Alpena County	1	Alpena	
Cheboygan County	1	Cheboygan	
Montmorency City	1	Atlanta	
Presque Isle	1	Rogers City	
DISTRICT HEALTH DEPARTMENT #5 - (616) 592-0130			1,200
Manistee County	1	Manistee	
Oceana County	1	Hart	
Newago County	1	White Cloud	
Lake County	1	Baldwin	
Mecosta County	1	Big Rapids	
Mason County	1	Ludington	
HURON-SANILAC-TUSCOLA ASSOC HEALTH DEPTS - (517) 269-9721			1,250
Sanilac County	1	Sandusky	
Tuscola County	1	Caro	
Huron County	1	Bad Axe	
LMAS HEALTH DEPT - (906) 293-5107			240
Luce County	1	Newberry	
Mackinac County	1	St. Ignace	
Alger County	1	Munising	
Schoolcraft County	1	Manistique	
CHIPPEWA COUNTY HEALTH DEPARTMENT - (906) 635-1568			344
	1	Sault Ste. Marie	
DETROIT CITY HEALTH DEPARTMENT - (313) 876-4000			5,000
	9	Detroit	
LENAWEE COUNTY HEALTH DEPARTMENT - (517) 264-5202			500
	1	Adrian	
MARQUETTE COUNTY HEALTH DEPARTMENT - (906) 475-9977			500
	1	Marquette	
ST CLAIR COUNTY HEALTH DEPARTMENT - (313) 987-5300			750
	2	Port Huron	
	1	Algonac	
	1	Yale	
WASHTENAW COUNTY HEALTH DEPARTMENT - (313) 484-6640			500
	2	Ann Arbor	

Summary:

11 Participating Local Health Departments
27 Counties Served
39 Screening Clinic Sites

MICHIGAN'S BREAST AND CERVICAL CANCER CONTROL PROJECT SITES

COHORT #2

Pending final contract negotiations, the following seven agencies (comprising Cohort #2) are expected to begin offering breast and cervical cancer screening and follow-up services to low income women by September 1992:

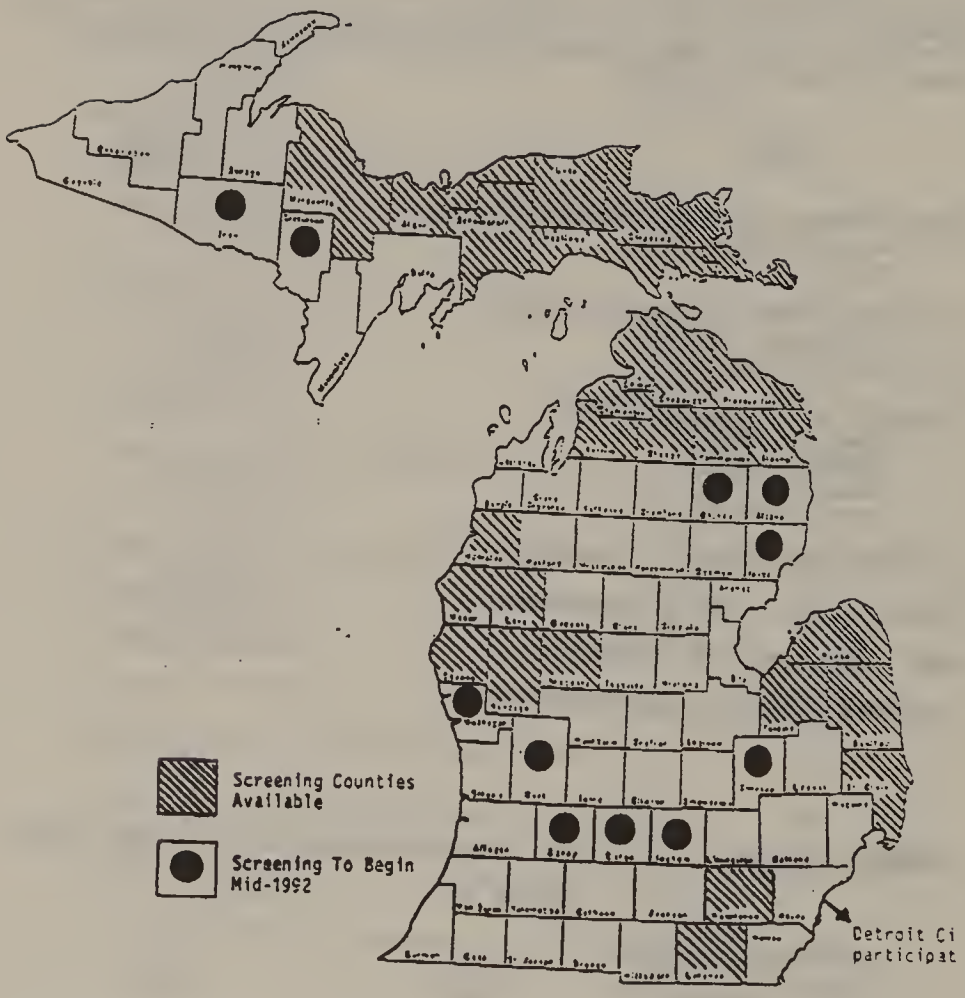
Agency	First Year Client Caseload
BARRY-EATON DISTRICT HEALTH DEPARTMENT Barry County Eaton County	650
DICKINSON-IRON HEALTH DEPARTMENT Dickinson County Iron County	500
DISTRICT HEALTH DEPARTMENT #2 Ogemaw County Alcona County Iosco County Oscoda County	1,500
GENESEE COUNTY HEALTH DEPARTMENT	500
INGHAM COUNTY HEALTH DEPARTMENT	2,000
KENT COUNTY HEALTH DEPARTMENT	2,000
MUSKEGON COUNTY HEALTH DEPARTMENT	1,250

SUMMARY: Breast and Cervical Cancer Program Participation, 1992

	Cohort #1	Cohort #2:
Screening Agencies	11	7
Counties Served	27	12
Women Screened*	13,342	8,400

* numbers anticipated to be screened after 12 months of services by each participating agency

MICHIGAN BREAST AND CERVICAL CANCER CONTROL PROJECT COUNTIES
(COHORTS #1 & 2)



NATIONAL ASSOCIATION FOR HOME CARE
Statement for the Record
on the

Clinical Laboratories Improvement Amendments of 1988

Subcommittee on Oversight and Investigations
Committee on Energy and Commerce

U.S. House of Representatives
Washington, D.C.

The National Association for Home Care (NAHC) is the nation's largest professional organization representing nearly 6,000 home care providers and hospices throughout the country. On behalf of our members and the patients they serve, we wish to impress upon this panel the importance of retaining blood glucose monitoring tests on the waivered list established by the Secretary of Health and Human Services (HHS) as required by the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

The final rules published on February 28, 1992, list glucose monitoring tests in the waivered category. This means that home care agencies that choose to continue performing routine tests using blood glucose monitoring devices cleared by the Food and Drug Administration (FDA) for home use, such as a glucometer, must apply for a certificate of waiver. NAHC believes that the Health Care Financing Administration has appropriately placed glucose monitoring devices in the waivered category.

Failure to retain blood glucose monitoring devices on the waivered list would require that these home care agencies meet additional burdensome requirements, including on-site surveys, proficiency testing, paperwork, registration and survey fees and the retention of additional personnel, including a laboratory director.

NAHC believes that these additional requirements are unnecessary to ensure safe usage of the glucometer. In addition, NAHC believes these additional requirements would duplicate many mandates agencies must now meet to participate in the Medicare and Medicaid programs, as well as programs providing private accreditation and many state licensure laws. Moreover, the FDA reports that a vast majority of adverse incidents do not occur in the home.

In medicine, risks are present however small, even with the simplest procedure or test. However, NAHC believes that several unique factors contribute to a smaller risk of specimen mismanagement in the home care setting.

Home care nurses are assigned to serve patients on the basis of the nurse's place of residence in order to minimize his/her travel time. As a result, home care patients are generally seen by the same nurse from week to week, thereby assuring a thorough familiarity of their condition by the nurse. Familiarity with patient eating habits and activity levels are important factors in evaluating tests obtained with a glucometer.

Continuity of care is recognized as desirable in institutional settings as well. However, personnel shortages and financial restraints have increased some provider's patient to nurse ratios. These factors have also made institutions increasingly dependent on contract nurses to fill gaps in their shifts. Continuity of care can deteriorate under these circumstances, with patients being seen by very busy nursing personnel who must rely exclusively on a kardex which briefly summarizes the patient's condition.

NAHC's research indicates that of the 286 reports filed with the FDA between May 1, 1989 and April 30, 1990 on glucose monitoring devices, only 5% of the reports were from incidents (such as equipment malfunctions and errors) occurring in the home. The remaining 95% of the reports were from incidents occurring in an institutional setting.

Further research indicates that these same incidents were related to poor equipment maintenance due to lack of education on the part of the operator, both nurse and patient. Performing tests in the waivered category requires the nurse to follow the manufacturers' instructions for performing the test. This would be operationalized by home care agencies through in-service training of staff. It is important to note that the Medicare conditions of participation and many state licensure and accreditation programs require in-service training and education appropriate to the services being provided by the agency.

The FDA recently established a new reporting system for incidents related to the use of medical devices. NAHC contributed significantly to the development of this new system which includes greatly enhanced reporting forms. These new forms will provide better information as to the nature of the incident, the location of the incident and whether the operator was a patient or a medical professional.

In conclusion, NAHC strongly urges the retention of blood glucose monitoring devices on the waivered test list. At a minimum, NAHC believes it would be premature to consider removing the blood glucose monitoring devices from the waivered list until a more thorough review can be conducted from data collected from the new FDA reporting system.

It is our belief that, should these tests be placed in a higher category requiring duplicative, unjustified and costly requirements, unnecessary costs will be incurred by home care agencies and the Medicare program.

NAHC appreciates the opportunity to comment on the implementation of the Clinical Laboratory Improvement Amendments of 1988.

Val J. Halamandaris
President

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HEARING STATEMENT

IMPLEMENTATION OF CLIA '88

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

APRIL 29, 1992

The Renal Physicians Association (RPA) is taking this opportunity to comment on the February 28, 1992 final rule implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88).

RPA is the national medical specialty organization, representing over 1700 nephrologists. Our organization is committed to ensuring optimum care under the highest standards of medical practice for patients with renal disease and related disorders.

As renal physicians we are specifically concerned about the quality of clinical lab testing in both our offices and in dialysis facilities. In our previous comments on the proposed rule, RPA voiced concern over the stringency of the regulation as it would affect free-standing dialysis facilities. Although our concerns about costs remain, we commend HCFA for substantially revising the regulation in terms of its effect on all laboratories. Specifically, the final rule is a big improvement over the proposed rule in terms of access to laboratory testing, personnel requirements, and the regulatory scheme, known as the "complexity model," created to classify the level of regulation needed for every clinical lab. RPA especially applauds the Health Care Financing Administration (HCFA) and the Centers for Disease Control (CDC) for creating this complexity model which classifies the level of regulation for laboratories based on the complexity of the methods employed, e.g., automated, semi-automated, and manual, as opposed to the proposed rule which classified labs merely by analyte.

We remain seriously concerned, however, about the costs to dialysis facilities and nephrologists' office laboratories, and about the time-frame for phase-in of implementation of the regulation given the obvious necessity to educate the medical profession on compliance. Enormous educational efforts will be required to ensure a smooth and fair implementation of the CLIA requirements; and it will take considerable cooperation between the medical profession, HCFA, and state agencies. In this regard, RPA is available and encouraged to work with all concerned parties.

Although the fees for compliance are the subject of another final rule (without a comment period), RPA is compelled to discuss the financial burden the costs for compliance will have on dialysis facilities. As you may know, dialysis facilities are reimbursed under the Medicare End-Stage Renal Disease program via a capped amount called the composite rate. And, since virtually all of a dialysis facilities revenues come from Medicare's composite rate, this makes it impossible to shift costs elsewhere. Additionally, since the composite rate has not been updated since 1983 and more and more services are provided for the same capitated amount, the CLIA financial

(One copy to RPA office, please)

burden will be ever the more painful for dialysis facilities to sustain. For these and other reasons, we urge HCFA to update the composite rate and build in to it the costs of CLIA compliance among other additional costs that facilities have had and continue to absorb. We realize that the law specifies that the CLIA program, including all costs for compliance, be sustained by user fees, but the regulation remains silent on those users, such as dialysis facilities whose costs are almost exclusively borne by the Medicare program. RPA believes that this is a disservice to the ESRD population.

RPA has heard no discussion on raising the lab fee schedule for clinical lab tests billed under the Medicare program, nor have we heard discussions on the cost-shifting to the private sector which we intuitively know will take place wherever possible to sustain the costs of CLIA compliance for testing performed for Medicare patients. As in the case of any uncompensated care, costs are usually shifted to the private sector. It is unfair and unrealistic to expect dialysis facilities and nephrologists who are both paid under capitated amounts (which are also in dire need of updates) and who do not have the ability to cost-shift to continue to absorb the costs of additional regulations without proper funding.

RPA fully supports quality control mechanisms and oversight in dialysis facilities, and therefore, the intent of the CLIA '88 statute. Fifty cents per dialysis treatment is paid toward funding the ESRD networks, which as you may know, are the HCFA run organizations which monitor quality in all dialysis facilities. These networks provide quality assurance in all aspects of care provided to patients in dialysis facilities including clinical lab testing. Additional existing oversight mechanisms include the evaluation of quality in dialysis facilities by state surveyors as is required for state and later Medicare certifications. Given these already existing quality assurance oversight mechanism, RPA is concerned that another layer of bureaucracy would be overkill for dialysis facilities who already fund the networks to assure quality, and which would unnecessarily add to the costs of operating a facility and the CLIA effort.

RPA is equally committed to ensuring quality in the nephrologist's office. While we note that HCFA has made major changes for the final rule as they relate to the categorization of tests, we are seriously concerned about the placement of microscopic analysis of urinary sediment in the moderate complexity category. RPA understands that this test has been placed in this category because it requires some training to perform. However, all physicians receive considerable training during medical residency to perform this test. Microscopic analysis of urine is an integral part of the evaluation of patients with renal problems; and in most nephrologists' offices this is the only clinical lab test they perform. Compliance fees to perform this one test would be cost-prohibitive for the nephrologist's office. In addition, the unavailability of immediate test results in the physician's office could reduce the overall quality of care provided. RPA therefore urges HCFA to add to the list of waived tests microscopic analysis of urinary sediment when personally performed by a physician on his or her own patient.

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